AMENDED IN SENATE APRIL 18, 2005

AMENDED IN SENATE JANUARY 6, 2005

SENATE BILL No. 19

Introduced by Senator Ortiz
(Principal coauthor: Senator Poochigian)

December 6, 2004

An act to add Division 112 (commencing with Section 130600) to the Health and Safety Code, relating to pharmacy~~—assistance,~~ *assistance,* and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 19, as amended, Ortiz. California Rx Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug~~—manufactures~~ *manufacturers* are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California *State* Pharmacy Assistance Program (Cal Rx) under the oversight of the department. The bill would authorize the department to implement and administer Cal Rx through a contract with a 3rd-party vendor or utilizing existing health care service provider enrollment and payment mechanisms. The bill would require the department~~—or 3rd-party vendor~~ to attempt to negotiate~~-drug~~ *manufacturer* rebate agreements for Cal Rx with drug manufacturers. The bill would authorize any licensed pharmacy and any drug manufacturer, as defined, to provide services under Cal Rx. The bill would establish eligibility criteria and application procedures for California residents to participate in Cal Rx. The application process would require an applicant to attest to information provided

under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program. ~~The bill would authorize the department to terminate the program if any one of 3 determinations are made.~~

The bill would establish the California State Pharmacy Assistance Program Fund into which all payments received under Cal Rx would be deposited. The bill would continuously appropriate the fund to the department for purposes of Cal Rx.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: 2/3. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Division 112 (commencing with Section 130600) is added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA STATE PHARMACY ASSISTANCE PROGRAM (CAL RX)

CHAPTER 1. GENERAL PROVISIONS

130600. This division shall be known, and may be cited, as the California State Pharmacy Assistance Program or Cal Rx.

130601. For the purposes of this division, the following definitions shall apply:

(a) "Benchmark price" means the price for an individual drug or aggregate price for a group of drugs offered by a manufacturer equal to the lowest commercial price for the individual drug or group of drugs.

(b) "Cal Rx" means the California State Pharmacy Assistance Program.

(c) "Department" means the State Department of Health Services.

(d) "Fund" means the California State Pharmacy Assistance Program Fund.

(e) "Inpatient" means a person who has been admitted to a hospital for observation, diagnosis, or treatment and who is expected to remain overnight or longer.

(f) (1) "Lowest commercial price" means the lowest purchase price for an individual drug, including all discounts, rebates, or free goods, available to any wholesale or retail commercial class of trade in California.

(2) Lowest commercial price excludes purchases by government entities, purchases pursuant to Section 340B of the federal Public Health Services Act (42 U.S.C. Sec. 256b), or nominal prices as defined in federal Medicaid drug rebate agreements.

(3) A purchase price provided to an acute care hospital or acute care hospital pharmacy may be excluded if the prescription drug is used exclusively for an inpatient of the hospital.

(4) Wholesale or retail commercial class of trade includes distributors, retail pharmacies, pharmacy benefit managers, health maintenance organizations, or any entities that directly or indirectly sell prescription drugs to consumers through licensed retail pharmacies, physician offices, or clinics.

(g) "Manufacturer" means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.

(h) ~~"Manufacturers~~ *"Manufacturer's* rebate" means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.

(i) *"Multiple-source drug" means the same drug in the same dosage form and strength manufactured by two or more manufacturers, which is approved by the United States Food and Drug Administration under provisions pertaining to the Abbreviated New Drug Applications (ANDA) process.*

(j) "National Drug Code" or "NDC" means the unique 10-digit, three-segment number assigned to each drug product listed under Section 510 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360). This number identifies the labeler or vendor, product, and trade package.

(k) "Participating manufacturer" means a drug manufacturer that has contracted with the department to provide an individual

drug or group of drugs for Cal Rx participants at a price that is equal to or lower than the benchmark price.

(l) "Participating pharmacy" means a pharmacy that has executed a pharmacy provider agreement with the department for Cal Rx.

(m) "Pharmacy contract rate" means the negotiated per prescription reimbursement rate for drugs dispensed to Cal Rx recipients.

(n) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only,"or words of similar import.

~~(j)~~

(o) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third-party payer program.

~~(k)~~

(p) "Recipient" means a resident that has completed an application and has been determined eligible for Cal Rx.

~~(l)~~

(q) "Resident" means a California resident pursuant to Section 17014 of the Revenue and Taxation Code.

~~(m) "Third-party vendor" means a public or private entity with whom the department contracts pursuant to subdivision (b) of Section 130602, which may include a pharmacy benefit administration or pharmacy benefit management company.~~

(r) "Therapeutic category" means a drug or a grouping of drugs determined by the department to have similar attributes and to be alternatives for the treatment of a specific disease or condition.

130602. (a) There is hereby established the California State Pharmacy Assistance Program or Cal Rx.

(b) The department shall provide oversight of Cal Rx. To implement and administer Cal Rx, the department may contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary.

(c) Any resident may enroll in Cal Rx if determined eligible pursuant to Section 130605.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCESS

130605. (a) To be eligible for Cal Rx, an individual shall meet all of the following requirements at the time of application and reapplication for the program:

(1) Be a resident.

(2) Have family income, as reported pursuant to Section 130606, that does not exceed 300 percent of the federal poverty guidelines, as revised annually by the United States Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902), as amended.

(3) Not have outpatient prescription drug coverage paid for in whole or in part by any of the following:

(A) A third-party payer. *An individual who has reached the annual limit on his or her outpatient prescription drug coverage provided by a third-party payer shall also be eligible for Cal Rx if he or she meets the eligibility requirements pursuant to paragraphs (1) and (2).*

(B) The Medi-Cal program.

(C) The children's health insurance program.

~~(D) The disability medical assistance program.~~

~~(E)~~

(D) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any other provision of this division to the contrary, an individual enrolled in Medicare may participate in this program, to the ~~extent allowed by federal law, for prescription drugs not covered by Medicare.~~ *extent allowed by federal law and consistent with federal state pharmacy assistance program standards, for prescription drugs not covered by Medicare prescription drug coverage or with respect to an individual responsible for paying 100 percent of the cost of prescription drugs under the coverage gap provisions of the Medicare Program prescription drug benefit.*

(4) Not have had outpatient prescription drug coverage specified in paragraph (3) during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, unless any of the following applies:

(A) The third-party payer that paid all or part of the coverage filed for bankruptcy under the federal bankruptcy laws.

(B) The individual is no longer eligible for coverage provided through a retirement plan subject to protection under the Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001), as amended.

(C) The individual is no longer eligible for the Medi-Cal program, children's health insurance program, or disability medical assistance program.

(D) The individual is no longer eligible for prescription drug coverage due to loss of employment and is not eligible for continued prescription drug coverage through the previous employer.

(b) Application and an annual reapplication for Cal Rx shall be made pursuant to subdivision (d) of Section 130606. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.

130606. (a) The department or third-party vendor shall develop an application and reapplication form for the determination of a resident's eligibility for Cal Rx.

(b) The application, at a minimum, shall do all of the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application.

(2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(3) Include a statement printed in bold letters informing the applicant that knowingly making a false statement is punishable under penalty of perjury.

(4) Specify that the application and annual reapplication fee due upon submission of the ~~applicable form~~ *application form through a pharmacy, physician office, or clinic* is fifteen dollars ($15).

(c) In assessing the income requirement for Cal Rx eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) Application and annual reapplication may be made at any pharmacy, physician office, or clinic participating in Cal Rx~~; through a Web site or call center staffed by trained operators approved by the department, or through the third-party vendor.~~. A pharmacy, physician office, clinic, or third-party vendor completing the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in Cal Rx, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a recipient.

(e) *Application and annual reapplication may be made through a Web site or call center staffed by trained operators approved by the department.*

(f) The department or third-party vendor shall utilize a secure electronic application process that can be used by a pharmacy, physician office, or clinic, by a Web site, by a call center staffed by trained operators, or through the third-party vendor to enroll applicants in Cal Rx.

~~(f) During normal~~

(g) During the department's regular business hours, the department or third-party vendor shall make a determination of eligibility within four hours of receipt by Cal Rx of a completed application. The department or third-party vendor shall mail the recipient an identification card no later than four days after eligibility has been determined.

~~(g)~~

(h) For applications submitted through a pharmacy, the department or third-party vendor may issue a recipient identification number for eligible applicants to the pharmacy for immediate access to Cal Rx.

(i) Any person that signs and dates an application shall certify that the information in the application is true under penalty of perjury.

130607. (a) *The department shall encourage a participating manufacturer to maintain the level of private discount drug programs provided at a comparable level to that provided prior to the enactment of this division. To the extent possible, the department shall encourage a participating manufacturer to simplify the application and eligibility processes for its private discount drug program.*

(b) The department or third-party vendor shall attempt to execute agreements with private discount drug programs to provide a single point of entry for eligibility determination and claims processing for drugs available in those private discount drug programs.

~~(b)~~

(c) (1) Private discount drug programs may require an applicant to provide additional information, beyond that required by Cal Rx, to determine the applicant's eligibility for discount drug programs.

(2) An applicant shall not be, under any circumstances, required to participate in, or to disclose information that would determine the applicant's eligibility to participate in, private discount drug programs in order to participate in Cal Rx.

(3) Notwithstanding paragraph (2), an applicant may voluntarily disclose or provide information that may be necessary to determine eligibility for participation in a private drug discount program.

~~(c)~~

(d) For those drugs available pursuant to subdivision ~~(a)~~ *(b)*, the department or third-party vendor shall develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private discount drug programs.

~~(d)~~

(e) The recipient identification card issued pursuant to subdivision ~~(g)~~ *(h)* of Section 130606 shall serve as a single point of entry for drugs available pursuant to subdivision ~~(a)~~ *(b)* and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130615. (a) To the extent that funds are available, the department shall conduct outreach programs to inform residents about Cal Rx and private drug discount programs available through the single point of entry as specified in subdivisions ~~(a)~~ *(b)* and ~~(d)~~ *(e)* of Section 130607. No outreach material shall contain the name or likeness of a drug. The name of the organization sponsoring the material pursuant to subdivision (b)

may appear on the material once and in a font no larger than 10 point.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform residents about Cal Rx. Neither Section 11005 of the Government Code, nor any other law requiring approval by a state officer of a gift, bequest, or donation shall apply to these gifts, bequests, or donations. For purposes of this section, outreach services may include, but shall not be limited to, coordinating and implementing outreach efforts and plans. Outreach materials may include, but shall not be limited to, brochures, pamphlets, fliers, posters, advertisements, and other promotional items.

(c) An advertisement provided as a gift, bequest, or donation pursuant to this section shall be exempt from Article 5 (commencing with Section 11080) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

(d) The department may negotiate a contract with any manufacturer to provide funds as grants to nonprofit programs pursuant to Division 2 (commencing with Section 5000) of Title 1 of the Corporations Code, for the purpose of conducting outreach for Cal Rx.

130616. (a) Any pharmacy licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2 of the Business and Professions Code may participate in Cal Rx.

(b) Any manufacturer, as defined in subdivision (g) of Section 130601, may participate in Cal Rx.

130617. (a) This division shall apply only to prescription drugs dispensed to noninpatient recipients.

(b) The amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract rate pursuant to subdivision (c), plus a dispensing fee that shall be negotiated as part of the rate pursuant to subdivision (c), less the applicable ~~manufacturers~~ *manufacturer's* rebate.

(c) The department or third-party vendor may contract with participating pharmacies for a rate other than the pharmacist's usual and customary rate. However, the department must approve the contracted rate of a third-party vendor.

(d) The department or third-party vendor shall provide a claims processing system that complies with all of the following requirements:

(1) Charges a price that meets the requirements of subdivision (b).

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides a single point of entry for access to private discount drug programs pursuant to Section 130607.

(4) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8(g)).

(e) The department or third-party vendor shall pay a participating pharmacy the discount provided to recipients pursuant to subdivision (b) by a date that is not later than two weeks after the claim is received.

(f) The department or third-party vendor shall develop a program to prevent the occurrence of fraud in Cal Rx.

(g) The department or third-party vendor shall develop a mechanism for recipients to report problems or complaints regarding Cal Rx.

(h) A participating pharmacy is not precluded from offering the recipient a pharmacy contract reimbursement rate pursuant to subdivision (c) for prescription drugs produced by manufacturers not participating in Cal Rx.

130618. (a) In order to secure the discount required pursuant to subdivisions (b) and (c) of Section 130617, the ~~department or third-party vendor shall attempt to negotiate drug~~ *department shall attempt to negotiate manufacturer* rebate agreements for Cal Rx with drug manufacturers. *The department shall pursue manufacturer rebate agreements for all drugs in each therapeutic category.*

~~(b) Each drug rebate agreement shall do all of the following:~~

(b) Each participating manufacturer rebate agreement executed pursuant to this division shall do all of the following:

(1) Specify which of the *participating* manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the *participating* manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

(6) Require the *participating* manufacturer to make the rebate payments to the department on at least a quarterly basis.

(7) Require the *participating* manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).

~~(8) Permit a~~

(8) Require the participating manufacturer to report to the department the lowest commercial price at the NDC level for each drug available through Cal Rx.

(9) Require the participating manufacturer to pay interest on late or unpaid rebates pursuant to subdivision (h).

(10) Permit a participating manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx. Claims information provided to manufacturers shall comply with all federal and state privacy laws that protect a recipient's health information.

(11) Contain provisions for the timely reconciliation and payment of rebates and interest penalties on disputed units.

(12) Permit the department to audit or review participating manufacturer records and contracts as necessary to implement this division.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available within Cal Rx.

(d) *To obtain the most favorable discounts on multiple-source drugs, the department may contract with private or public purchasing groups.*

(e) The entire amount of the drug rebates negotiated pursuant to this section shall go to reducing the cost to Cal Rx recipients of purchasing drugs. The Legislature shall annually appropriate an amount to cover the state's share of the discount provided by this section.

~~(e)~~

(f) The department or third-party vendor may collect prospective rebates from *participating* manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to this section.

~~(f) Drug rebate contracts negotiated by the third-party vendor shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or Cal Rx recipients.~~

(g) The third-party vendor may directly collect rebates from manufacturers in order to facilitate the payment to pharmacies pursuant to subdivision (e) of Section 130617. The department shall develop a system to prevent diversion of funds collected by the third-party vendor.

(h) (1) A participating manufacturer shall calculate and pay interest on late or unpaid rebates.

(2) Interest described in paragraph (1) shall begin accruing 38 calendar days from the date of mailing the quarterly invoice, including supporting utilization data sent to the manufacturer. Interest shall continue to accrue until the date the manufacturer's payment is mailed.

(3) Interest rates and calculations for purposes of this subdivision shall be at ____ percent.

(i) A participating manufacturer shall clearly identify all rebates, interest, and other payments, and payment transmittal forms for Cal Rx, in a manner designated by the department.

130619. (a) The department or third-party vendor shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) A Summary of the problems or complaints reported regarding Cal Rx.

(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.

130620. (a) The department or third-party vendor shall deposit all payments received pursuant to Section 130618 into

the California State Pharmacy Assistance Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, moneys in the fund are hereby appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130617 and for defraying the costs of administering Cal Rx. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

(c) Notwithstanding Section 16305.7 of the Government Code, any interest earned on any rebates collected from participating manufacturers on drugs purchased through Cal Rx implemented pursuant to this chapter shall be deposited in the fund exclusively to cover costs related to the purchase of drugs through Cal Rx.

130621. The department may hire any staff needed for the implementation and oversight of Cal Rx.

130622. The department shall seek and obtain confirmation from the federal Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) and that discounts provided under the program are exempt from Medicaid best price requirements.

130623. (a) Contracts and change orders entered into pursuant to this division and any project or systems development notice shall be exempt from all of the following:

(1) The competitive bidding requirements of State Administrative Manual Management Memo 03–10.

(2) Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(3) Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of the Government Code.

(b) Change orders entered into pursuant to this division shall not require a contract amendment.

~~130624. The department may terminate Cal Rx if the department makes any one of the following determinations:~~

~~(a) That there are insufficient discounts to participants to make Cal Rx viable.~~

~~(b) That there are an insufficient number of applicants for Cal Rx.~~

~~(c) That the department is unable to find a responsible third-party vendor to administer Cal Rx.~~

(c) Drug rebate contracts entered into pursuant to this division are exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

130625. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this division in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 19 **VERSION: AMENDED APRIL 18, 2005**

AUTHOR: ORTIZ **SPONSOR: DEPT. OF HEALTH SERVICE GOVERNOR**

RECOMMENDED POSITION:

SUBJECT: CALIFORNIA Rx PROGRAM

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1. Establishes the California State Pharmacy Assistance Program (Cal Rx, program) within the Department of Health Services (DHS). (H&S 130600 Added)

2. Permits DHS to contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. (H&S 130602 Added)

3. Defines the terms: benchmark price, Cal Rx, fund, inpatient, lowest commercial price, manufacturer, manufacturer's rebate, prescription drug, private discount drug program, recipient, resident, third-party vendor, multiple-source drug, national drug code, participating manufacturer, participating pharmacy, pharmacy contract rate, and therapeutic category. (H&S 130600 Added)

4. Establishes eligibility criteria for the program as:

   a. A resident of California who has a family income does not exceed 300 percent of the federal poverty guidelines. (2005 - $28,710 for an individual and $58,050 for a family of four)

   b. A family that does not have outpatient prescription drug coverage paid for in whole or in part by any of the following: a third-party payer, the Medi-Cal program, the children's health insurance program, or another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. (H&S 130605Added)

5. Set a yearly fee of $15 for application or reapplication for the program. (H&S 130606 Added)

6. Requires DHS or third party vendor to establish a Web site and call center to use for applying for the program. Additionally requires DHS or third party vendor to determine eligibility for the program within four hours of receipt of a completed application. (H&S 130606 Added)

7. Permits DHS to conduct an outreach program to inform California residents of their opportunity to participate in program, if funds are available. (H&S 130615 Added)

8. Requires DHS to negotiate drug rebate agreements with drug manufacturer's to provide for discounts for prescription drugs purchased through the program. (H&S 130618 Added)

9. Sets the amount a recipient pays for a drug within program as equal to the pharmacy contract rate, plus a dispensing fee that shall be negotiated by DGS, less the applicable manufacturer's rebate. (H&S 130616 Added)

Comment:

1) Author's Intent. This bill is sponsored by the Governor and is in response to last year's veto of SB 1149 (Ortiz 2004). In his veto message the Governor stated, "A top priority of my Administration is to provide access to affordable prescription drugs. However, importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians. California Rx represents an approach that harnesses the purchasing power of low-income seniors and uninsured Californians up to 300% of the federal poverty level ($28,710 for an individual and $58,050 for a family of four) to secure meaningful discounts in prescription drug costs. My Administration has begun negotiations with pharmaceutical companies regarding their participation in California Rx."

A fact sheet issued by the author's office states "In addition to the discounted drugs available to Cal Rx participants, Governor Schwarzenegger has secured a commitment from the Pharmaceutical Researchers and Manufacturers Association (PhRMA) to provide $10 million over the next two fiscal years to fund a clearinghouse to publicize and help Californians enroll in manufacturers' free and discount programs. The clearinghouse will provide Internet access and a toll-free multi-lingual call center to help thousands of Californians receive prescription drugs absolutely free, thereby saving them hundreds of millions of dollars per year. This element of the program does not require legislation and will begin operating in Spring 2005."

2) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty- five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

3) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

4) Related Legislation.

AB 75 (Frommer) Pharmaceutical Assistance Program, would establish the California Rx Plus State Pharmacy Assistance Program within DHS. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program. The measure establishes eligibility for the program for families with incomes equal to or less than 400 percent of the federal poverty guidelines.

5) Support / Opposition.

Support: State Department of Health Services (sponsor)
AARP
AIDS Healthcare Foundation
Alzheimer's Association
American Russian Medical Association
Asthma & Allergy Foundation of America
BayBio
BIOCOM
CA Academy of Family Physicians
CA Arthritis Foundation Council
CA Black Chamber of Commerce
CA Council of Community Mental Health Agencies
CA Healthcare Institute
CA Hepatitis C Task Force
CA Latino Medical Association
CA Medical Association
CA Pharmacists Association
CA Psychiatric Association
CA Society of Health-System Pharmacists
Down Syndrome Information Alliance
Epilepsy Foundation
Generic Pharmaceutical Association (if amended)
Gray Panthers California (if amended)
Hemophilia Council of California
Hispanic-American Allergy Asthma and Immunology Association
Lambda Letters Project
Mental Health Association in California
NAMI California
National Multiple Sclerosis Society - California Action Network
Novartis

Osteopathic Physicians and Surgeons of California
Pharmaceutical Research and Manufacturers of America
TMJ Society of California

Opposition: California Alliance for Retired Americans
California Federation of Teachers
California School Employees Association, AFL-CIO
International Alliance of Theatrical State
Employees, Moving Picture Technicians, Artists, and Allied Crafts of the United States
Amalgamated Transit Union Local 1555
Unless American Federation of Government Employees, Local 1061
American Federation of State, County, & Municipal Employees
American Federation of Television and Radio Arts
Butchers' Union Local 120
CA Conference Board of the Amalgamated Transit Union
CA Conference of Machinists
CA Labor Federation,
CA Nurses Association
CA Professional Firefighters
CA Public Interest Research Group
CA Teamsters Public Affairs Council
Central Labor Council of Butte, Contra Costa, and Glenn Counties
Consumer Federation of California
Communications Workers of America (CWA), Local 9412
CWA, Locals 9415, 9423, 9431, 9503, and 9586
Engineers and Scientists of California Local 20, IFPTE
Graphic Communications Union, Local 583
Greenlining Institute
Health Access California
Industrial, Technical and Professional Employees Union, Local 4873
International Alliance of Theatrical Stage Employees, Local 16
International Association of Machinists and Aerospace Workers, District Lodge 947
International Brotherhood of Electrical Workers (IBEW), Local 6 IBEW, Locals 45, 302, 441 and 569
International Cinematographers Guild Local 600
Ironworkers Locals 433 and 509
Kern County Fire Fighters Union Inc.
Laborers' International Union of North America
Laborers' International Union of North America, Local 89
League of United Latin American Citizens
National Association of Broadcast Employees and Technicians, Local 53
National Association of Chain Drug Stores
National Association of Letter Carriers, Golden Gate Branch 214, AFL-CIO
Northern California District Council - ILWU
Office of Professional Employees International Union, AFL-CIO, CLC
Orange County Central Labor Council, AFL-CIO
Plumbers and Pipefitters UA, Local 62
Professional and Technical Engineers, Local 21, IFPTE
Professional Musicians, Local 47
Sailors' Union of the Pacific
San Diego Imperial Counties Labor Council, AFL-CIO
San Francisco Labor Council, AFL-CIO
San Mateo Building and Construction Trades Council

San Mateo County Central Labor Council Santa Clara & San Benito Counties
Building & Construction Trades Council
Senior Action Network
Service Employees International Union (SEIU), AFL-CIO
SEIU, Locals 660, 1280, and 2028
SEIU of United Healthcare Workers - West
Sheet Metal Workers' International Association Local Unions 104 and 206
Southern California District Council of Laborers
Strategic Committee of Public Employees, Laborers International Union
Teamsters Local Unions 683 and 896
Teamsters Locals 912and 853
Teamsters Union Locals 572, 601, and 630
Transport Workers Union of America, AFL- CIO
Tri-Counties Central Labor Council
UFCW Locals 428, 1428, 1442, and 1179 UNITE-HERE! AFL-CIO UNITE-HERE! Locals 19 and 49
United Professional Firefighters of Contra Costa County,IAFF Local 1230
United Teachers Los Angeles

6) History.

2005	
May 4	Hearing postponed by committee.
Apr. 28	Set for hearing May 4 pending suspension of rules.
Apr. 27	Set, first hearing. Failed passage in committee. (Ayes 5. Noes 5. Page 845.) Reconsideration granted.
Apr. 21	Set for hearing April 27.
Apr. 20	Hearing postponed by committee.
Apr. 18	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Apr. 14	Set for hearing April 20.
Apr. 13	Testimony taken. Hearing postponed by committee.
Mar. 17	Set for hearing April 13.
Jan. 27	To Com. on HEALTH.
Jan. 6	To Com. on RLS. From committee with author's amendments. Read second time. Amended. Re-referred to committee.
2004	
Dec. 7	From print. May be acted upon on or after January 6.
Dec. 6	Introduced. Read first time. To Com. on RLS. for assignment. To print.

BILL ANALYSIS
SB 19

SENATE HEALTH
COMMITTEE ANALYSIS
Senator Deborah V. Ortiz, Chair

AUTHOR: Ortiz
AMENDED: April 18, 2005
HEARING DATE: April 20, 2005
FISCAL: Appropriations

CONSULTANT: Bohannon / ak

TESTIMONY TAKEN - VOTE ONLY

SUBJECT

California Rx Program

SUMMARY

This bill would establish the California State Pharmacy Assistance Program (Cal Rx), a state pharmacy assistance program under the authority of the Department of Health Services (DHS), to provide prescription drug discounts for California residents with income up to 300% of the federal poverty level (FPL).

ABSTRACT

Existing federal law:

1. Requires, for the purposes of the federal Medicaid program, drug manufacturers to enter into rebate agreements with the United States Secretary of Health and Human Services (the Secretary) for states to receive federal funding for outpatient prescription drugs dispensed to Medicaid enrollees.

2. Defines Medicaid "best price" as the lowest price paid to a manufacturer for a brand name drug, taking into account rebates, chargebacks, discounts or other pricing adjustments, excluding nominal prices.

3. Requires manufacturers under agreement with the Secretary to provide rebates to state Medicaid agencies for outpatient prescription drugs provided to Medicaid beneficiaries. For brand name drugs, requires the amount of the rebate owed to be the greater of 15.1% of the average manufacturers price (AMP) or the difference between AMP and the best price. Requires rebates for

generic drugs to be 11% of AMP.

4.Excludes the prices charged to certain governmental purchasers from best price provisions including prices charged to the Veterans Administration, Department of Defense, Indian tribes, Federal Supply Schedule, state pharmaceutical assistance programs (SPAPs), Medicaid, and 340B covered entities.

5.Permits a state, upon authorization from the Secretary, to enter directly into agreements with drug manufacturers to negotiate deeper (supplemental) discounts for state Medicaid programs.

6.Specifies that a state may require, as a condition of coverage or payment for a covered outpatient drug, the approval of the drug before its dispensing if the system of providing for such approval meets specified criteria.

Existing federal guidance:

1.Authorizes states to establish SPAPs for the purposes of providing pharmaceutical benefits for low-income non-Medicaid eligible residents.

2.Establishes the following criteria for federal SPAP designation:

The program is a state developed program specifically for disabled, indigent, low-income elderly or other financially vulnerable persons;

The program is funded by the state; that is, no federal dollars are involved;

The program is set up so that payment is provided
The program provides either a pharmaceutical benefit only or a pharmaceutical benefit in conjunction with other medical benefit or services; and,

The program does not allow for the diversion, resale or transfer of benefits reimbursed under the SPAP to individuals who are not beneficiaries of the SPAP.

Existing state law:

1.Establishes the Medi-Cal program, California's Medicaid program, which provides health insurance coverage and prescription drug benefits for low-income families, children, and aged, blind, and disabled individuals.

2.Authorizes DHS to be the purchaser of prescribed drugs

under the Medi-Cal program in order to obtain the most favorable prices from drug manufacturers. Authorizes DHS to obtain discounts, rebates, or refunds based on the quantities purchased by the program, as permissible by federal law.

3.Defines "state rebate" as any negotiated rebate under the Drug Discount Program (Medi-Cal) in addition to the Medicaid rebate.

4.Authorizes DHS to enter into contracts with drug manufacturers, on a bid or nonbid basis, for drugs from each therapeutic category and requires DHS to maintain a list of those drugs for which contracts have been executed.

5.Authorizes DHS or the state's fiscal intermediary to impose prior authorization requirements on the drug products of manufacturers for which DHS has not received rebate or interest payments as specified.

6.Exempts specified drugs from prior authorization requirements and authorizes the director of DHS to exempt any drug from prior authorization if it is determined that an essential need exists for that drug and there are no other drugs available without prior authorization that meet that need.

7.Requires all manufacturers to provide DHS with a state rebate, in addition to rebates pursuant to other provisions of state or federal law, for any drug products added to the Medi-Cal list of contract drugs and those reimbursed through the Medi-Cal outpatient fee-for-service drug program. Renders this provision inoperative on July 1, 2005 and repealed January 1, 2006, unless otherwise extended or repealed.

8.Authorizes DHS to use existing administrative mechanisms for any drug for which DHS does not obtain a rebate.

9.Provides that no beneficiary be denied continued use of a drug that is part of a prescribed therapy that is the subject of an administrative mechanism until the prescribed therapy is no longer prescribed.

This bill:
1.Establishes Cal Rx, a SPAP, under the authority of DHS.

2.Provides that to be eligible for Cal Rx, individuals must meet all of the following requirements:
Be a resident;

Have family income that does not exceed 300% of FPL;

Not have outpatient prescription drug coverage paid for in part or in whole by a third-party payer (exempts individuals who have reached the annual cap on their prescription drug coverage), the Medi-Cal program, the children's health insurance program, another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of an individual's outpatient prescription drug costs.

Medicare beneficiaries may participate to the extent allowed by federal law and SPAP standards for prescription drugs not covered by Medicare prescription drug coverage or those currently responsible for paying 100% of the cost of a prescription drug under the coverage gap provisions of the Medicare prescription drug benefit.

Not have had outpatient prescription drug coverage during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, with certain exceptions.

1. Requires application and annual reapplication and establishes program application criteria and procedures. Specifies that the application and annual reapplication fee due upon submission through a pharmacy, physician office, or clinic is $15.

2. Requires DHS to use the income information reported on the application and not require additional documentation.

3. Authorizes a pharmacy, physician office, or clinic to keep the fee as reimbursement for its processing costs. The fee shall be returned to the applicant if the applicant is already enrolled in Cal Rx.

4. Specifies that application and annual reapplication may also be made through a Web Site or call center staffed by trained operators approved by DHS.

5. Requires DHS or a third party vendor to utilize a secure electronic application process that can be utilized to enroll applicants in Cal Rx.

6. Requires DHS or a third party vendor, during regular business hours, to make an eligibility determination within 4 hours of receipt of a Cal Rx completed application.

7. Requires applicants to certify under penalty of perjury that the information in the application is true.

8.Requires DHS to encourage participating manufacturers to maintain their private discount drug programs at a level comparable to which they were offered prior to the enactment of Cal Rx and, to the extent possible, simplify the application and eligibility processes for those programs.

9.Requires DHS or a third party vendor to attempt to execute agreements with private discount drug programs to provide a single point of entry for eligibility determination and claims processing for drugs available in those programs.

10. Prohibits an applicant from having to disclose information that would determine eligibility for a private drug discount program in order to participate in Cal Rx.

11. Requires DHS or a third party vendor to develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private drug discount programs.

12. Requires the recipient to be issued an identification card, which shall meet the legal requirements for a uniform prescription drug card.

13. Requires DHS to conduct outreach programs to the extent that funds are available. Prohibits the outreach material from containing the name or likeness of a drug. Specifies that the name of the organization sponsoring the material may appear on the material once and in a font no larger than 10 point.

14. Allows DHS to accept, on behalf of the state, any gift, bequest, or donation of outreach services or materials to inform residents about Cal Rx. Exempts these gifts and advertisements provided as gifts as specified.

15. Authorizes DHS to negotiate a contract with any manufacturer to provide funds as grants to nonprofit programs for the purpose of conducting outreach for Cal Rx.

16. Authorizes any licensed pharmacy and manufacturer, as defined, to participate in Cal Rx.

17. Specifies that the amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract

rate, as defined, plus a dispensing fee, less the applicable manufacturers rebate.

18. Requires DHS or a third party vendor to provide a claims processing system as specified.

19. Requires DHS to attempt to negotiate manufacturer rebate agreements for Cal Rx with drug manufacturers. Requires DHS to pursue manufacturer rebate agreements for all drugs in each therapeutic category.

20. Requires each participating manufacturer rebate agreement to:

Specify which drugs are included in the agreement.

Permit DHS to remove a drug from the agreement in a dispute over the drug's utilization.

Require the manufacturer to make a rebate payment for each drug specified.

Require the rebate payment for a drug be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

Define a unit, for the purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

Require the manufacturer to make the rebate payments to DHS on at least a quarterly basis.

Require the manufacturer to provide documentation to validate the per unit rebate.

Require the manufacturer to report to DHS the lowest commercial price, as specified, for each drug available through Cal Rx.

Require the manufacturer to pay interest on late or unpaid rebates.

Permit a manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx.

Contain provisions for the timely reconciliation of payment of rebates and interest penalties on disputed units.

Permit DHS to audit or review manufacturer records and contracts as necessary.

1.Authorizes DHS to limit the number of drugs available within Cal Rx to obtain the most favorable discounts.

2.Authorizes DHS to contract with private or public purchasing groups to obtain the most favorable discounts

3.Requires the entire amount of the negotiated drug rebates to go towards reducing the cost to Cal Rx recipients of purchasing drugs.

4. Authorizes DHS or a third party vendor to collect prospective rebates from manufacturers for payment to pharmacies. Authorizes a third party vendor to directly collect rebates from manufacturers in order to facilitate the payment to pharmacies. Requires DHS to develop a system to prevent the diversion of funds.

5. Requires participating manufacturers to calculate and pay interest on late or unpaid rebates, which shall begin accruing 38 calendar days from the date of mailing the quarterly invoice.

6. Specifies that interest rates and calculations shall be "X" percent.

7. Requires participating manufacturers to clearly identify all rebates, interest, and other payments for Cal Rx in a manner designated by DHS.

8. Requires DHS or a third party vendor to generate a monthly report as specified.

9. Establishes the California State Pharmacy Assistance Program Fund in the State Treasury and requires DHS or a third party vendor to deposit all payments received as specified.

10. Specifies that moneys in the fund are appropriated to DHS without regard to fiscal years for the purpose of providing payment to participating pharmacies and for defraying the costs of administrating Cal Rx. Specifies that no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

11. Requires that interest earned on rebates collected from participating manufacturers also be deposited in the fund exclusively to cover costs related to the purchase of drugs through Cal Rx.

12. Authorizes DHS to hire any staff needed for the implementation and oversight of Cal Rx.

13. Requires DHS to seek and obtain confirmation from the Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a SPAP.

14. Exempts contracts and change orders entered into from competitive bidding requirements and specified provisions of the Public Contract and Government Codes.

15. Specifies that change orders entered into shall not require contract amendment.

16. Exempts drug rebate contracts entered into from disclosure under the Public Records Act.

17. Permits the director to implement this division in whole or in part by means of provider bulletin or other similar instructions, without taking regulatory action.

18. Requires that no reimbursement be required pursuant to Section 6 of Article XIII B of the California Constitution.

FISCAL IMPACT

The Governor's FY 05-06 budget plan for DHS appropriates $3.9 million dollars from the General Fund for program staff and administrative costs. Unknown one-time costs associated with the timing of rebates and initial payments to pharmacies.

BACKGROUND AND DISCUSSION

Rising prescription drug costs
As a number of studies document, access to affordable prescription drugs is a growing problem in California and in the US. According to the Kaiser Family Foundation (KFF), almost a quarter of Americans under age 65 have no prescription drug coverage. In California, according to the UCLA Center for Health Policy Research, nearly one in five Californians under age 65 lacked health coverage altogether in 2001, a substantial percentage of whom are not eligible for most public assistance or drug assistance programs due to excess income or assets. Of those who do have health coverage, over 2 million report that they do not have coverage for prescription drugs.

Further, prescription drugs represent one of the fastest growing health care expenditures as drug prices continue to grow at roughly twice the rate of inflation in California and the rest of the U.S. Of the 50 drugs used most frequently by seniors, the average annual cost as of January 2003 was $1,439. The five most frequently prescribed medications for the elderly all had annual costs of between $500 and $1,500 per year. According to surveys, substantial percentages of seniors forego taking their medications due to the high cost.

Canadian importation
In an effort to facilitate immediate access to affordable

prescription drugs for seniors and people with disabilities, several members of the legislature introduced bills that would have allowed the importation of prescription drugs from Canada in some capacity. Although it is currently illegal, an estimated 1 million Americans buy drugs from Canada, accounting for at least $1 billion in annual sales. According to various sources, comparable drugs in Canada sell for 40 percent less than in the U.S. on average, and can sometimes sell for 50 - 70 percent less, because the Canadian government limits what drug companies can charge for prescription drugs. In addition, exchange rates can contribute to lower costs of Canadian drugs.

The Food and Drug Administration's (FDA) consistent policy has been that foreign medicines are unsafe because they cannot assure that they are not counterfeit, mislabeled, expired, or contaminated. Although it cannot point to cases in which US residents have been harmed by drugs purchased from foreign pharmacies, the FDA cites evidence from several border checks of drugs bound for consumers in the US that have found large percentages of unidentified drugs, counterfeit drugs, mislabeled drugs, and drugs not approved for use in the U.S.

The FDA has adopted a personal importation policy which permits individuals and physicians to import up to a three-month supply of drugs for treatment of a patient's condition for which effective treatment may not be available domestically, which do not present an unreasonable risk, and for which there is no intent to market to U.S. residents. In practice, the FDA generally has not prosecuted individuals who are importing drugs for their own use.

In a letter dated August 19, 2004, the Secretary of the Health and Human Services Agency expressed concern that the importation measures were contrary to federal law and would expose the state to potential tort liability. As an alternative approach, the Secretary proposed amending the bills to establish a SPAP to harness the purchasing power of low-income seniors and uninsured Californians to secure prescription drug discounts from pharmaceutical manufacturers.

Governor Arnold Schwarzenegger, subsequently, sent a letter to Tommy Thompson, Secretary of the U.S. Department of Health and Human Services, detailing his concern with the Canadian drug importation legislation and expressing his desire to reduce the costs of prescription drugs by establishing a drug discount program or by extending

Medi-Cal prescription drug prices to targeted low-income uninsured residents.

On September 21, 2004, the Senate Health and Human Services Committee held an informational hearing on the Administration's pharmacy assistance proposal where representatives from DHS provided a detailed overview of the proposal including the estimated discounts, number of enrollees, and timeline for implementation. The committee also heard extensive testimony from representatives from senior and consumer advocacy organizations who believed the administration's proposal needed considerably more work before it could provide the band of discounts available under a Canadian importation model.

State Pharmaceutical Assistance Programs (SPAPs)
SPAPs refer to a broad category of state policies designed to help residents pay for prescription drugs. States submit program proposals meeting specified criteria to the federal government in order to receive a SPAP designation. This designation incentivizes manufacturer participation by exempting the prices the state negotiates for program beneficiaries from Medicaid "best price" laws, thereby allowing the state to negotiate deeper drug discounts. As of August 2004, at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number use discounts or bulk purchasing approaches. Many of these programs were established prior to the enactment of the Medicare prescription drug benefit and provide an opportunity for states to provide "wrap around" coverage to Medicare beneficiaries who will be receiving prescription drug benefits under Medicare. SPAPs usually provide discounts using the following mechanisms:

Medicaid Rate. Enrollees will pay no more than the state's Medicaid price. An additional pharmacy dispensing fee may be added to the drug price, but that is generally set by the program and, therefore, the same across all pharmacies. Enrollees will pay the same amount for a particular manufacturer's drug at all pharmacies that participate in the program.

Manufacturer Rebates. Some states will negotiate directly with manufacturers for lower drug prices. These states then set a drug price for program enrollees that are based on the state-negotiated price.

Medicaid Rebate. The drug discount is based on the manufacturers' rebates through the state's Medicaid programs.

Pharmacy Benefits Manager (PBM)-Negotiated Rate. The PBMs negotiate discounts with manufacturers and pharmacists. If the state uses multiple PBMs, the discounted price will vary.

Maine and the Medicaid "Hammer"

Maine's Act to Establish Fairer Prices for Prescription Drugs was enacted in 2000, and established the MaineRx program, which was open to all residents who did not have prescription drug coverage. Under MaineRx, the state was to serve as a PBM by negotiating rebates and discounts, with the discount offered by pharmacies being reimbursed by the state out of funds raised from participating manufacturer rebates.

Pharmacy participation was voluntary, but compulsory for manufacturers with Medicaid contracts in the state. MaineRx provided disincentives for nonparticipating manufacturers, such as subjecting their drugs to prior authorization requirements in the state Medicaid program (the "hammer") and advertising their refusal to participate to health care providers and the public.

MaineRx was immediately challenged by the pharmaceutical industry. PhRMA sued the state, won a preliminary injunction from the federal district court, and then lost a subsequent appeal by the state before a federal court of appeals panel. In particular, the appellate court rejected PhRMA's argument that MaineRx's prior authorization requirement was inconsistent with federal Medicaid law. The appellate court further found that the local benefits of the program outweighed any incidental burdens on interstate commerce. In July 2001, PhRMA asked the U.S. Supreme Court to review the decision.

On May 19, 2003, the U.S. Supreme Court ruled 6 to3 that the MaineRx Program was not preempted because the Medicaid Act "gives the States substantial discretion to choose the proper mix of amount, scope and duration limitations on coverage, as long as care and services are provided in the best interest of the recipients." The Court also ruled that the MaineRx statute on its face did not violate the Interstate Commerce Clause.

The legislature revised MaineRx soon after the Supreme Court acted by creating the MaineRx Plus program. The new

program requires participating pharmacies to provide drugs that are on Maine's Medicaid preferred drug list to state residents whose family income is 350% or less of the FPL or whose family incurs unreimbursed prescription drug expenses equal to 5% or more of family income or unreimbursed medical expenses of 15% or more of family income.

As of January 2004, pharmacies began providing drugs to MaineRx Plus participants at the same cost as Medicaid participants pay. If the state is able to negotiate further discounts, pharmacies must offer the drugs at this lower price, and the state must reimburse them for the price difference. The new program does not include the $3 dispensing fee that pharmacies were to receive under MaineRx.

The MaineRx law required the state to impose prior authorization requirements in its Medicaid program on drug manufacturers and drug labelers that did not participate in the program. MaineRx Plus softens this somewhat, by removing the mandatory requirement and instead granting the state the authority to impose prior authorization if DHS determines that doing so is an appropriate way to encourage manufacturer participation and is consistent with the state Medicaid plan and federal law. It makes the names of manufacturers and labelers who do not provide rebates public information and requires DHS to release them to the public and health care providers. The names of manufacturers and labelers who provide rebates also become public, and DHS is supposed to publicize their participation. As with MaineRx, the manufacturers' rebates are to be paid into a dedicated fund that is used to reimburse pharmacies for the drug discounts and DHS for contracted services related to the program, including pharmacy claims processing fees.

In January 2005, the Federal District Court in Maine ruled that under the legal doctrine of "ripeness," it would be premature to conclude that the permissive prior authorization scheme in MaineRx Plus in any way violates federal Medicaid law; that we cannot know this unless and until it is actually applied and we can factually determine whether any Medicaid beneficiaries were hurt by its use. The court stated that since the Maine statute explicitly requires prior authorization be implemented only "as permitted by law" and "in a manner consistent with the goals of the MaineCare program and the requirements of the Social Security Act," it is possible for Maine to implement its prior authorization without violating the law. The court concluded that while the Maine program was not

reviewable at this time, due to lack of ripeness, it remains subject to review by the Secretary of Health and Human Services at the appropriate time.

Arguments in support
Supporters of the bill, including AARP, the California Medical Association, and several disease management groups across the state insist that SB 19 is an important first step in providing significant and immediate relief to those who are paying the highest costs for their prescription drugs. They insist that the proposal will deliver discounts of 40% to 70% off the retail price of prescription drugs and provide nearly 5 million low-income Californians better access to private drug discount programs which often offer free or deeply discounted prescription drugs.

They believe that Cal Rx is an essential element in the complex care system that will support the needs of seniors and persons with disabilities and chronic conditions who have reduced incomes due to their limited ability to work or in the case of those who are dependant, limited income due to family members who must give their own jobs in order to be caregivers. They insist that the discounts this proposal contemplates should be given the opportunity to materialize before more aggressive measures that could potentially risk the health and well-being of our most vulnerable seniors, children, and persons with disabilities are pursued. They believe that SB 19 is the only legislative proposal that provides the best hope of being implemented quickly and with relatively low risk of litigation.

Arguments in opposition
Opponents of SB 19 raise the following concerns:

1.Lowest commercial price as a benchmark
Opponents believe the lowest commercial price is a fictitious price that is not commonly known and has not been adequately referenced in the bill. They insist that SB 19 should include a more commonly recognized benchmark price such as the Medicaid price for DHS to target in drug company negotiations. They insist that using the Medicaid price would also reduce the administrative overhead required, since the prices of the Medi-Cal program are already known to the state.

2.Income eligibility
Opponents insist that given California's high cost of living, SB 19's income eligibility should be expanded to cover individuals with income up to 400% of the federal

poverty level. They insist that many Californians most in need of drug discounts are those who are sick and underinsured. They also believe that individuals who spend significant portions of their incomes on medications also deserve discounted prices.

3.Drug availability
Opponents of the bill argue that SB 19 allows pharmaceutical manufacturers to determine which drugs will be included in the discount program and for what period of time. They believe SB 19 contains no assurance that the drugs that are the highest cost to the uninsured or the most frequently needed by affected populations will be included.

4.Outreach
Opponents of the bill believe that it is problematic to allow DHS to accept branded outreach materials from drug manufacturers for use in a public health program.

5.Lack of Medicaid leverage or "hammer"
Opponents of SB 19 insist that participation by pharmaceutical manufacturers and pharmacists is entirely voluntary leaving the state without a mechanism to punish those who fail to provide drug discounts. They insist that the bill's exclusive reliance on voluntary participation provides little assurance that any drug discounts the state is able to secure will be maintained. They believe that rather than relying on voluntary participation, SB 19 should be amended to allow the state to impose prior authorization requirements in the Medi-Cal program if a drug manufacturer refuses to offer meaningful discounts in Cal Rx.

Prior / relevant legislation
AB 73 (Frommer, 2005) provides information to consumers about international pharmacies that meet state standards for safety and accessibility. Set for hearing in the Assembly Health Committee on April 12, 2005.

AB 75 (Frommer, 2005) establishes a state pharmacy assistance program for Californians with income up to 400% of the federal poverty level. Set for hearing in the Assembly Health Committee on April 12, 2005.

AB 76 (Frommer, 2005) consolidates drug purchasing for state programs to negotiate lower drug prices. Set for hearing in the Assembly Health Committee on April 12, 2005.

AB 77 (Frommer, 2005) creates a pilot program for the

California Department of Corrections to purchase prescription drugs at federal discount prices. Set for hearing in the Assembly Health Committee on April 12, 2005.

SB 1333 (Perata, 2004) allowed DHS to reimburse pharmacies for drugs dispensed to Medi-Cal and AIDS Drug Assistance Program beneficiaries that were purchased from a Canadian pharmacy, and established a new reimbursement rate for such drugs. Vetoed by the Governor.

SB 1144 (Burton, 2004) required Canadian sources be included among the companies with which the Department of General Services (DGS) is permitted to contract for prescription drugs, that all contracts include appropriate safeguards, and that DGS seek appropriate federal waivers. Vetoed by the Governor.

SB 1149 (Ortiz, 2004) required the Board of Pharmacy to develop a website that included information on Canadian pharmacies that met recognized standards for safe dispensing of drugs to California residents and information concerning prescription drugs suppliers outside the United States that violated safe dispensing standards. Vetoed by the Governor.

AB 1957 (Frommer, 2004) required DGS to coordinate a review of state agencies to determine potential savings if prescription drugs were purchased from Canada and to establish pilot programs. Required DHS to establish a California Rx Program, including a website to facilitate purchasing prescription drugs at reduced prices. Required the website to include price comparisons, including Canadian prices and links to Canadian pharmacies. Vetoed by the Governor.

QUESTIONS AND COMMENTS

1.The Maine Mystery. The MaineRx Plus program is widely regarded as the vanguard of prescription drug policy at the state level; however the success of MaineRx Plus remains ambiguous. It is currently unclear what level of discounts the program has been able to secure on brand name and generic drugs and to what extent those discounts are derived from manufacturer rebates. Additionally, it is also uncertain whether or not Maine's "hammer", their statutory authority to place the drugs of non-MaineRx Plus-participating manufacturers on prior authorization in the state Medicaid program, has encouraged or discouraged manufacturer participation.

According to the Legislative Analyst's Office (LAO), Maine's program has secured rebates with 20 drug companies for 200 drugs with prices up to 60% below the retail pharmacy price. However, other sources indicate that the state has only secured discounts of up to 15% for brand name drugs and 60% for generics through voluntary agreements with drug manufacturers, while others maintain that the state has not begun negotiating with drug manufacturers at all.

What is clear, however, is that MaineRx Plus is not an SPAP. Arguably, federal SPAP designation is the "hammer" that incentivizes manufacturer participation and allows states to negotiate deep discounts. If California is able to secure SPAP designation for Cal Rx, the program could negotiate discounts far below what MaineRx Plus is currently able to provide. The LAO recommends a "hybrid hammer" approach whereby, the state would move forward with a voluntary program, but would require the director of DHS to automatically phase out the voluntary model if drug manufacturers fail to participate. In such a circumstance, the eligibility standard for the program would automatically be expanded to 400% of the federal poverty level.

Should this bill be amended to include benchmark and accountability measures to measure manufacturer participation and program discounts over time and to determine whether a more stringent approach is needed?

If such leverage could increase manufacturer participation, secure significantly deeper discounts, and be implemented in such a way that it is consistent with federal law and the goals of the Medicaid program, including preserving prescription drug access for the most vulnerable Medi-Cal beneficiaries, without jeopardizing federal SPAP designation, should it be considered for this proposal?

1. Income Eligibility and Catastrophic Coverage. While 300% of the federal poverty guideline covers more than 75% of California's uninsured, arguably some provision should be made for individuals with higher incomes who, because of chronic conditions, must spend a disproportionate amount of their family income on unreimbursed medical expenses or prescription drug costs. MaineRx Plus extends eligibility to all residents whose family incurs unreimbursed prescription drug expenses and unreimbursed medical expenses equal to 5% and 15% or more of family income, respectively.

California's AIDS Drug Assistance Program (ADAP), an SPAP for individuals infected with HIV/AIDS, sets program eligibility at 400% of the FPL. ADAP establishes state precedent for moving beyond 300% of the FPL due to exorbitant prescription drug costs and medical necessity.

Federal SPAP designation requires that a program be means tested and specifically designed to serve low-income vulnerable populations. While Maine's generous catastrophic coverage provision would probably not meet federal approval, the author may wish to consider including some form of catastrophic coverage, within the bounds of federal SPAP criteria, to expand program eligibility to this population.

POSITIONS

POSITIONS

Support: State Department of Health Services (sponsor)
AARP
AIDS Healthcare Foundation
Alzheimer's Association
American Russian Medical Association
Asthma & Allergy Foundation of America
BayBio
BIOCOM
CA Academy of Family Physicians
CA Arthritis Foundation Council
CA Black Chamber of Commerce
CA Council of Community Mental Health Agencies
CA Healthcare Institute
CA Hepatitis C Task Force
CA Latino Medical Association
CA Medical Association
CA Pharmacists Association
CA Psychiatric Association
CA Society of Health-System Pharmacists
Down Syndrome Information Alliance
Epilepsy Foundation
Generic Pharmaceutical Association (if amended)
Gray Panthers California (if amended)
Hemophilia Council of California
Hispanic-American Allergy Asthma and Immunology Association
Lambda Letters Project
Mental Health Association in California
NAMI California
National Multiple Sclerosis Society - California Action Network
Novartis

Osteopathic Physicians and Surgeons of California
Pharmaceutical Research and Manufacturers of America
TMJ Society of California

Oppose:
California Alliance for Retired Americans
California Federation of Teachers
California School Employees Association, AFL-CIO
International Alliance of Theatrical State
Employees, Moving Picture Technicians, Artists, and Allied Crafts of the United States
Amalgamated Transit Union Local 1555
Unless American Federation of Government Employees, Local 1061
American Federation of State, County, & Municipal Employees
American Federation of Television and Radio Arts
Butchers' Union Local 120
CA Conference Board of the Amalgamated Transit Union
CA Conference of Machinists
CA Labor Federation,
CA Nurses Association
CA Professional Firefighters
CA Public Interest Research Group
CA Teamsters Public Affairs Council
Central Labor Council of Butte, Contra Costa, and Glenn Counties
Consumer Federation of California
Communications Workers of America (CWA), Local 9412
CWA, Locals 9415, 9423, 9431, 9503, and 9586
Engineers and Scientists of California Local 20, IFPTE
Graphic Communications Union, Local 583
Greenlining Institute
Health Access California
Industrial, Technical and Professional Employees Union, Local 4873
International Alliance of Theatrical Stage Employees, Local 16
International Association of Machinists and Aerospace Workers, District Lodge 947
International Brotherhood of Electrical Workers (IBEW), Local 6 IBEW, Locals 45, 302, 441 and 569
International Cinematographers Guild Local 600
Ironworkers Locals 433 and 509
Kern County Fire Fighters Union Inc.
Laborers' International Union of North America
Laborers' International Union of North America, Local 89
League of United Latin American Citizens
National Association of Broadcast Employees and Technicians, Local 53
National Association of Chain Drug Stores
National Association of Letter Carriers, Golden Gate Branch 214, AFL-CIO
Northern California District Council - ILWU
Office of Professional Employees International Union, AFL-CIO, CLC
Orange County Central Labor Council, AFL-CIO
Plumbers and Pipefitters UA, Local 62
Professional and Technical Engineers, Local 21, IFPTE
Professional Musicians, Local 47
Sailors' Union of the Pacific

San Diego Imperial Counties Labor Council, AFL-CIO
San Francisco Labor Council, AFL-CIO
San Mateo Building and Construction Trades Council
San Mateo County Central Labor Council Santa Clara & San Benito Counties Building & Construction Trades Council
Senior Action Network
Service Employees International Union (SEIU), AFL-CIO
SEIU, Locals 660, 1280, and 2028
SEIU of United Healthcare Workers - West
Sheet Metal Workers' International Association Local Unions 104 and 206
Southern California District Council of Laborers
Strategic Committee of Public Employees, Laborers International Union
Teamsters Local Unions 683 and 896
Teamsters Locals 912and 853
Teamsters Union Locals 572, 601, and 630
Transport Workers Union of America, AFL- CIO
Tri-Counties Central Labor Council
UFCW Locals 428, 1428, 1442, and 1179 UNITE-HERE! AFL-CIO UNITE-HERE! Locals 19 and 49
United Professional Firefighters of Contra Costa County,IAFF Local 1230
United Teachers Los Angeles

AMENDED IN ASSEMBLY MARCH 17, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 73

Introduced by Assembly Members Frommer and Chan
(Coauthors: Assembly Members *Baca,* Bass, *Berg, Coto, De La Torre,* Evans, *Goldberg,* Gordon, *Hancock, Klehs,* Koretz, *Leno, Levine,* Nava, Pavley~~, and Salinas~~, *Ridley-Thomas, Ruskin, Salinas, and Torrico*)

January 3, 2005

An act to ~~add Section 14982 to the Government Code, and to~~ add Article 5 (commencing with Section 110242) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 73, as amended, Frommer. Prescription drugs: importation: procurement.

~~(1)~~ Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

Existing law, the Pharmacy Law, provides that any pharmacy located outside of this state that delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state is considered a nonresident pharmacy and requires a nonresident pharmacy to register with the California State Board of Pharmacy and comply with all lawful directions of, and requests for information from, the state in which it is a resident.

Existing federal law requires any establishment within any foreign country engaged in the manufacture, preparation, propagation,

compounding, or processing of a drug that is imported or offered for import into the United States to register with the federal Secretary of Health and Human Services, report a list of each drug introduced for commercial distribution, and provide required information and statements.

This bill would establish the California Rx Prescription Drug Web Site Program. The bill would require the State Department of Health Services to administer the program and establish a Web site on or before July 1, 2006, to provide information to California residents about options for obtaining prescription drugs at affordable prices. The bill would require that the Web site, at a minimum, provide information about, and establish electronic links to, certain federal, state, and pharmaceutical programs, pharmacies that are located in Canada, ~~England~~ *the United Kingdom*, and Ireland and that meet specified requirements, and other Web sites.

This bill would authorize the department to assess a fee on international pharmacies that the department reviews for possible inclusion on the Web site to offset the cost of reviewing those pharmacies. The bill would require the department's Web site to include price comparisons of prescription drugs, including prices charged by licensed pharmacies in the state and international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site.

~~(2) Existing law authorizes the Department of General Services to administer a coordinated prescription drug bulk purchasing program under which the department may enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multisource drugs and obtain from them discounts, rebates, and refunds as permissible under federal law. Existing law requires certain state agencies to participate in the program and authorizes any other state, local, and public agency governmental entity to elect to participate in the program.~~

~~This bill would require the department to coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from sources other than those from which the state now purchases, including sources that meet the requirements to be listed on the California Rx Prescription Drug Web site. The bill would require the department, on or before January 1, 2007, to conduct the review and report to the Legislature. The bill would require the report to~~

~~recommend options to facilitate more cost-effective acquisition of prescription drugs. The bill would authorize the department to establish pilot programs under which purchases of prescription drugs from international pharmacies would be made at reduced prices for purposes of state departments and agencies.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Prescription drugs have become essential for ensuring the health of millions of Californians.

(b) The United States is the largest trade market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand name pharmaceuticals in the world.

(c) Increased spending on prescription drugs is a significant driver of increases in overall health care costs, with spending nationwide on prescription drugs rising over 15 percent each year from 2000 to 2002.

(d) Rising out-of-pocket costs for prescription drugs are placing a growing burden on California consumers, as evidenced by federal government statistics *that* show that in 2002 the increase in consumers' out-of-pocket costs for prescription drugs was greater than the increase in out-of-pocket costs for all other health care expenditures.

(e) The price of brand name drugs is rising faster than the rate of inflation, with a recent study showing that the price of 30 drugs most frequently used by the elderly rose by over four times the rate of inflation in 2003 and that some drugs increased in price by 10 times the rate of inflation in that year.

(f) The rising cost of prescription drugs also places a significant burden on state government, with the cost of providing prescription drugs to Medi-Cal beneficiaries, to inmates of the Department of Corrections, and to other participants in state programs growing in some cases at over 20 percent annually in recent years.

(g) The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford

the medication they need to stay healthy, as shown by a study by the RAND Corporation that found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over 20 percent and subsequently experienced higher rates of emergency room visits and hospital stays.

(h) The rising cost of prescription drugs places a disproportionate burden on communities of color, as shown in a report from the Center for Studying Health System Change that found that African-Americans are about 75 percent and Latinos about 50 percent more likely than nonminorities to not have purchased a prescription drug in 2001 because of cost issues.

(i) A prescription drug is neither safe nor effective to an individual who cannot afford it.

(j) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

~~SEC. 2. Section 14982 is added to the Government Code, to read:~~

~~14982. (a) The Department of General Services shall coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from sources other than those from which the state now purchases, including sources that meet the requirements of Section 110242 of the Health and Safety Code. State departments to be reviewed shall include, but not be limited to, all of the following:~~

~~(1) The State Department of Health Services.~~

~~(2) The Managed Risk Medical Insurance Board.~~

~~(3) The Department of General Services.~~

~~(4) The Department of Corrections.~~

~~(5) The California Public Employees' Retirement System (CalPERS).~~

~~(b) The Department of General Services shall, on or before January 1, 2007, conduct the review required under subdivision (a) and report its findings based on that review to the Legislature. The report shall recommend options to the Legislature, including conducting pilot programs, to facilitate more cost-effective acquisition of prescription drugs. The recommendations shall~~

~~include a determination of the need to seek any federal approvals or waivers.~~

~~(c) The Department of General Services may establish pilot programs under which purchases of prescription drugs from international pharmacies are made at reduced prices for purposes of state departments and agencies.~~

~~(d) As a condition of implementing any pilot program under this section, the Department of General Services shall seek and obtain all appropriate federal waivers and approvals necessary for the implementation of that pilot program.~~

~~SEC. 3.~~

SEC. 2. Article 5 (commencing with Section 110242) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California Rx Prescription Drug Web Site Program

110242. (a) The California Rx Prescription Drug Web Site Program is hereby established.

(b) The State Department of Health Services shall administer the program. The purpose of the program shall be to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.

(c) The department shall establish a Web site on or before July 1, 2006, which shall, at a minimum, provide information about, and electronic links to, all of the following:

(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program.

(2) State programs that provide drugs at discounted prices for California residents.

(3) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

(4) International pharmacies that provide mail-order service to the United States and who meet the requirements of paragraph (2) of subdivision (d).

(5) Other Web sites as deemed appropriate by the department that help California residents to safely obtain prescription drugs

at affordable prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.

(d) (1) The Web site shall include price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by licensed pharmacies in the state and by international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site pursuant to paragraph (2).

(2) The Web site shall provide information about, and establish electronic links to, pharmacies that are located in Canada, ~~England~~ *the United Kingdom*, and Ireland that provide mail-order services to the United States and that meet all of the following requirements:

(A) Are licensed by the province or country, as appropriate, in which they are located.

(B) Comply with the requirements of a nonresident pharmacy as specified in Section 4112 of the Business and Professions Code, except that for purposes of this section all references to "state" in subdivision (d) of Section 4112 of the Business and Professions Code shall be deemed to refer to the province or other licensing jurisdiction in which the pharmacy is located. Compliance with this subparagraph shall be determined by the department in consultation with the California State Board of Pharmacy.

(C) Require a prescription from a patient's personal physician, who is licensed to practice in the United States.

(D) Require the completion of a relevant medical history profile.

(E) Require a signed patient agreement.

(F) Ship prescription drugs in tamperproof original manufacturer containers to individuals in the United States, unless the consumer requests to receive the drug in a childproof container.

(G) Include a physical address and pharmacy license number on its company Web site.

(H) Do not furnish any of the following:

(i) A controlled substance.

(ii) A biological product, as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262).

(iii) An infused drug, including, a peritoneal dialysis solution.

(iv) An intravenously injected drug.

(v) A drug that is inhaled during surgery.

(vi) A drug that requires refrigeration or cannot be safely shipped by mail.

(vii) More than the prescribed amount of a drug or more than a three-month supply of any drug.

(viii) A drug that the consumer indicates he or she has not previously taken.

(ix) A drug for which there is no equivalent drug approved for sale in the United States by the federal Food and Drug Administration.

(I) Sell only prescription drugs that have been approved for sale in the country in which the pharmacy is located by the agency responsible for ensuring the safety of prescription drugs in that country.

(J) Comply with state law regarding the documentation of the pedigree of prescription drugs.

(K) Does not require a consumer to sign a waiver of liability or a release of liability for a negligent act by the pharmacy.

(L) Maintain a service department to respond to consumer inquiries and provide information to consumers about how they may file complaints with the provincial or other applicable licensing authority.

(M) Ensure that all physicians, pharmacists, and technicians in its employ are properly licensed and their licenses are in good standing.

(N) Comply with all personal health and medical information privacy laws applicable to pharmacies located in California.

(O) Any other requirement established by the department to ensure the safety, accessibility, and affordability of prescription drugs.

(3) A pharmacy that seeks to be linked to the department's Web site pursuant to paragraph (2) shall apply to the department. The department may enter into a contract with a pharmacy that it determines meets the requirements of paragraph (2). A contract may be renewed annually upon payment of the fee specified in paragraph (5) provided that the pharmacy continues to comply with the requirements of paragraph (2).

(4) The department may terminate a contract with, and delete an electronic link to, or information about, a pharmacy that the

department determines no longer complies with the requirements of paragraph (2). The department shall review within 30 business days any information that it receives regarding a pharmacy's compliance with the requirements of paragraph (2) and shall determine whether the information constitutes grounds for removal of the pharmacy from the Web site.

(5) The department may assess a fee on international pharmacies that the department reviews pursuant to paragraph (2) to offset the cost of reviewing those pharmacies.

(e) The department shall ensure that the Web site established pursuant to this section is coordinated with, and does not duplicate, other Web sites that provide information about prescription drug options and costs.

(f) Any information, including the identity of an international pharmacy, to be posted on the Web site shall first be approved by professional staff of the department before it is posted.

(g) The department shall include on the Web site a notice that informs consumers about state and federal laws governing the importation of prescription drugs and the federal Food and Drug Administration's policy governing personal importation. The notice shall also inform consumers that a pharmacy linked to the Web site is licensed in the country in which it is located and that the department has the right to remove a pharmacy from the Web site if it violates the requirements of paragraph (2) of subdivision (d) or the terms of any agreement between the department and the pharmacy. In addition, the notice shall include a statement that the state accepts no legal liability with respect to any product offered or pharmaceutical services provided by a pharmacy linked to the Web site.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 73 **VERSION: AS AMENDED MARCH 17, 2005**

AUTHOR: FROMMER et al. **SPONSOR: AUTHOR**

RECOMMENDED POSITION: NO POSITION

SUBJECT: DRUG IMPORTATION

Existing Law:

1) Requires non-resident pharmacies to be licensed by the board. (B&P 4112)

2) Prohibits the importation of prescription drugs except by a drug manufacturer. (21CFR 381)

This Bill:

1) Makes a number of legislative findings about the costs and necessity of prescription drugs.

2) Requires the Department of Health Services (DHS) to establish a Web site on or before July 1, 2006 that will provide consumers with information on how to purchase prescription drugs more affordably. The Web site would include the following information:

a. The availability of a prescription drug benefit through Medicare, including the Voluntary Prescription Drug Benefit.
b. Discount drug programs available through the state.
c. Discount drug programs operated by drug manufacturers.
d. Canadian pharmacies that are approved by the department.
e. International pharmacies (Canada, England, and Ireland) that provide mail order service to the Untied States and contract with the department.
f. Links to any other Web sites deemed appropriate by the department.

(H&S 110242 Added)

3) Requires the Web site to include price comparisons between typical pharmacy prices and international pharmacy prices for the 50 most commonly prescribed drugs.

(H&S 110242 Added)

4) Establishes the requirements that must be met for DHS to "certify" a pharmacy located in Canada, England, or Ireland to include:

a. Verification of licensure by the appropriate province or country.
b. Compliance with the requirements that must be met by non-resident pharmacies. This determination will be made in consultation with the board.
c. Requires a prescription from the patient's personal physician.
d. Requires a patient medical history.
e. Requires a signed patient agreement.

f. Requires prescriptions to be mailed in original packaging.
g. Requires physical address and phone number for the pharmacy on the pharmacy Web site.
h. Prohibits the pharmacy from furnishing the following drugs:
    i. Controlled substances.
    ii. Biologics.
    iii. Infused drugs.
    iv. Intravenous drugs.
    v. Drugs inhaled during surgery.
    vi. Drugs requiring refrigeration or that are otherwise inappropriate for mail delivery.
i. Sale of only drugs approved by the country in which the pharmacy is located.
j. Comply with California law relating to drug pedigree.
k. Prohibits requiring patients to sign a waiver of liability.
l. Requires the pharmacy to maintain a customer service department.
m. Requires the pharmacy to employ professionals that are licensed in good standing.
n. Requires the pharmacy to comply with California privacy laws.
o. Prohibits filling a prescription if the patient hasn't taken the drug previously.
p. Prohibits furnishing drugs that have no equivalent approved by the FDA.

(H&S 110242 Added)

5) Permits the department to remove approved pharmacies from the Web site if the pharmacy fails to meet any of the above listed requirements. (H&S 110242 Added)

6) Permits the department to assess a fee on international pharmacies to fund this act. (H&S 110242 Added)

Comment:

1) Author's Intent. The author's intent is to provide relief for Californians who are "fed up with sky-high pharmaceutical drug prices and concerned about the safety of those drugs." AB 73 is part of an eight-bill package being offered by Assembly Democrats to bring down the cost of prescription drugs sold in California.

2) Importation. Existing federal law generally restricts the importation of prescription drugs to drug manufacturers. Federal law can permit the importation of prescription drugs by drug wholesalers and pharmacies if the Secretary of Health and Human Services (Secretary) issues a finding that such a practice would be safe. Such a finding has not been issued by the Secretary.

The Food and Drug Administration (FDA) has for many years allowed individuals to purchase drugs abroad in limited amounts and bring them into the United States for personal use. Recent statements by FDA officials have reinforced that the FDA does not intend to prosecute individuals who import drugs for their own use. However, the FDA has taken legal action against some storefronts that assist consumers in ordering drugs from Canadian pharmacies at lower prices. The FDA has also taken legal action against entities that serve as middlemen between Canadian drug suppliers and those state and local governments that have sought to purchase Canadian drugs for their beneficiaries.

3) Price Controls. Consumers seek to purchase drugs from Canadian and EC pharmacies to save money. Drug prices are lower in Canada because the Canadian government has a system to control drug prices. ***Branded*** drugs can commonly be purchased from Canadian

pharmacies at substantial discounts. However, US prices are generally lower for ***generic*** drugs.

4) Affordability. The board has been sympathetic to the difficulty of those without drug insurance have to obtain the drugs they need.

Much of the public debate regarding the importation of drugs from Canada has focused on the safety of imported drugs. Consumers are seeking Canadian and EC drugs because of lower prices not because of problems with drug availability or because of the convenience of the Canadian pharmacies.

5) Federal Legislation. Three bills have been introduced in Congress that would amend the Federal Food, Drug, and Cosmetic Act to permit the importation of prescription drugs from outside the United States. The bills place limits on the types of drugs that could be imported and from which countries the importation can take place. The bills are S 334, HR 328 and HR 700; none of the bills has yet to be heard in committee.

6) Other States. Seven states (Illinois, Minnesota, Nevada, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

7) State Legislation. AB 1957 (Frommer et.al. 2004), Drug Importation, was introduced last session, AB 73 is similar to AB 1957 except AB 73 expands the list of countries for drug importation to include England and Ireland, or any other country. The board opposed AB 1957 and the Governor vetoed the measure. In the Governor's veto message he states "...importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability.... In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians."

8) Support & Opposition.

Support:

AIDS Healthcare Foundation
American Federation of State, County, and Municipal Employees
California Alliance of Retired Americans
California Federation of Teachers
California Labor Federation
California Medical Association
California Public Interest Research Group
California School Employees Association
California Teachers Association
City Council and City of Compton
Consumers Union
County of San Joaquin
Health Access California
Lieutenant Governor Cruz Bustamante
NAMI California
Older Women's League of California
Retired Public Employees Association
Senior Action Network
Service Employees International Union

Oppose:

BIOCOM
California Chamber of Commerce
California Health Institute
Pharmaceutical Research and Manufacturers of America

9) History.

2005

June 23	From committee: Do pass, and re-refer to Com. on B., P. & E.D. Re-referred. (Ayes 6. Noes 4.). Read second time, amended, and re-referred to Com. on APPR.
June 15	Referred to Coms. on HEALTH and B., P. & E.D.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 46. Noes 31. Page 2142.)
May 27	Read second time. To third reading.
May 26	From committee: Do pass. (Ayes 11. Noes 5.) (May 25).
May 4	In committee: Set, first hearing. Referred to APPR. suspense file.
Apr. 27	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 6. Noes 1.) (April 26).
Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 10. Noes 4.) (April 12).
Mar. 29	Re-referred to Com. on HEALTH.
Mar. 17	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

BILL ANALYSIS
AB 73

Date of Hearing: April 12, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
AB 73 (Frommer) - As Amended: March 17, 2005

SUBJECT : Prescription drugs: importation: procurement.

SUMMARY : Requires the Department of Health Services (DHS) to establish a Web site to facilitate purchasing prescription drugs at reduced prices. Requires the Web site to include price comparisons, including prices of, and links to, international pharmacies that meet specified requirements. Specifically, this bill :

1)Establishes the California Rx Prescription Drug Web Site Program, administered by DHS, to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.

2)Requires DHS to establish a Web site on or before July 1, 2006, to provide at a minimum information about, and electronic links to, all of the following:

a) Prescription drug benefits available to Medicare beneficiaries;

b) State programs that provide drugs at discounted prices for California residents;

c) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals;

d) Pharmacies in Canada, the United Kingdom, and Ireland that provide mail-order service to the United States and which meet specified requirements to assure safety, accessibility, and affordability of prescription drugs; and,

e) Other Web sites as deemed appropriate by DHS.

3)Requires the Web site to include price comparisons of at least 50 commonly prescribed brand name prescription drugs, as specified.

4)Permits DHS to enter into a contract with an international pharmacy that meets requirements specified in this bill.

Permits DHS to terminate a contract with, and delete an electronic link to, or information about, an international pharmacy that no longer complies with the requirements of this bill.

5)Requires a contracted international pharmacy to be licensed by the province or country in which it is located and to comply with the requirements of a nonresident pharmacy, as specified.

6)Permits DHS to assess a fee on international pharmacies to offset the cost of reviewing applications of those pharmacies.

7)Requires DHS to ensure that the Web site required by this bill is coordinated with, and does not duplicate, other Web sites that provide information about prescription drug options and costs. Requires that any information posted on the Web site first be approved by DHS professional staff.

8)Requires DHS to include on the Web site a notice that informs consumers about state and federal laws governing the importation of prescription drugs and the federal Food and Drug Administration's policy governing personal importation. Requires other specified notices.

EXISTING LAW :

1)Provides that any pharmacy located outside of California that delivers prescription drugs into the state is considered a nonresident pharmacy. Requires a nonresident pharmacy to register with the Board of Pharmacy and comply with all lawful directions of and requests for information from the state in which it is a resident.

2)Prohibits, under the federal law, the importation or reimportation of prescription drugs except by the original manufacturer.

FISCAL EFFECT : Unknown.

COMMENTS :

1)PURPOSE OF THIS BILL . According to the author, this bill provides relief from the high costs consumers are paying for prescription drugs. These high prices are hurting many Californians, including one-quarter of seniors who skip doses or fail to get medications because of cost. The author reports that the high cost of drugs has a disproportionate effect on African-Americans, who are 75% more likely than whites not to have bought a prescription drug because of cost. Latinos are 50% more likely than whites not to have bought drugs because they cannot afford them. As a result of these

high costs, the author notes that many consumers are turning to Canada and other countries, where brand-name drugs can be 30 to 75 % cheaper than in the United States. According to the author, this bill would enable the state of California to provide a valuable service to its residents by giving them information about safe, reputable mail-order pharmacies located in Canada, the UK and Ireland.

2)BACKGROUND . Spending on prescription drugs grew at a real (inflation-adjusted) average annual rate of 14.5% from 1997 to 2002. That rapid growth raised prescription drug spending's share of total health expenditures to 11% in 2003, compared with 5.8% a decade earlier. In 2003, American consumers paid $53.2 billion in out-of-pocket costs for prescription drugs, an increase of 26% over 2001.

Californians without drug coverage have been especially hard hit. Some must choose between food, rent, and needed medications. A 2003 Kaiser Family Foundation survey found that 37% of the uninsured, when they finally did see a doctor, did not fill a needed prescription because of cost. Even those with drug coverage, especially through Medicare HMOs and Medicare Supplement policies, find the cost of prescription drugs often far exceeds their coverage limits. Other insured Californians are hit with 3-tiered drug benefits, increased cost-sharing and decreased access to needed drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over 20% and experienced higher rates of emergency room visits and hospital stays. The Medicare Prescription Drug and Modernization Act of 2003 (MMA) will provide some relief to seniors when it takes effect on January 1, 2006. Even then many seniors will be responsible for significant out-of-pocket expenses. For instance, a senior with $5100 in drug spending will be responsible for $3600 of that amount in addition to an annual premium of at least $420.

The ever-increasing cost of prescription drugs has forced growing numbers of Americans, many of them elderly citizens living on fixed incomes, to buy essential medications from beyond U.S. borders. Each year, millions of Americans achieve some level of financial relief by purchasing prescription drugs from Canada, Mexico, Europe, and Southeast Asia. The recent development of Canadian Internet pharmacies has demonstrated the true demand for inexpensive medication. Researchers estimate that over six million Americans have obtained needed medicines from online Canadian pharmacies. The federal government estimates that consumer spending on drugs from Canada and other countries totaled $1.1 billion in 2003.

3)SAFETY CONCERNS . It is generally agreed that the Canadian regulatory systems for approving and distributing drugs is very similar to that in the US. In the US, the approval and marketing of prescription drugs is governed under the Federal Food, Drug, and Cosmetic Act, with enforcement administered by the Food and Drug Administration (FDA). In Canada, the approval and marketing practices are regulated under the Food and Drugs Act, with enforcement by the Therapeutic Products Directorate, an arm of Health Canada, which is responsible for assuring the safety and quality of all medicines sold in Canada. Both countries' statutes require drugs to be proven safe and effective through clinical studies and manufactured to strict quality standards before they can be approved and distributed for general use. In addition, both countries have analogous requirements for licensing of retail pharmacies and pharmacists; in Canada, licensing is conducted by provinces or territories, whereas in the U.S. it is done by states.

Studies by two federal agencies, the Congressional Research Service (CRS) and the Government Accountability Office, report that the drug distribution system in Canada is as safe as or safer than our own. The CRS study, for example, shows that Health Canada regulates the drug supply system in Canada in ways that make drug distribution there safer than in the U.S. because drugs pass through the hands of fewer middlemen, reducing the opportunity for counterfeit drugs to enter the supply chain. In June 2004, the GAO issued a report that found that Canadian internet pharmacies had safer pharmacy practices than American internet pharmacies. All of the Canadian pharmacies examined by the GAO required a prescription, for example, while only one in six American internet pharmacies did so. In contrast, a U.S. Department of Health and Human Services report, mandated by the MMA and released in December 2004, recommended against legalizing personal importation, after concluding it would result in significant safety risks, decreased research and development, liability issues and small national savings. The conclusions of the study were severely critiqued by proponents of importation as having been preordained.

4)FEDERAL LAW . Federal law allows only the manufacturer to import, or reimport, prescription drugs into the U.S. However, the FDA and U.S. Customs, because of their enforcement discretion and finite resources, have not enforced the importation ban on individuals bringing limited supplies of drugs for personal use across the border. Prescription drugs sent to American consumers through the mail also appear to enjoy the benefit of this enforcement discretion. Attempts to legalize importation at the federal level have been unsuccessful thus far. In each of the past 5 years a number measures to allow importation from Canada and other countries

have been introduced in both houses of Congress without success.

5)LIABILITY ISSUES . The author has received a formal opinion from Legislative Counsel regarding liability issues. Legislative Counsel has concluded that the state could be subject to liability for negligence under state law in limited circumstances, such as negligent ministerial errors committed by the Board or its employees (as in listing an incorrect pharmacy on the web site), unless the Legislature enacts a statute providing immunity from liability to cover those activities and the Board includes on its web site adequate notice and disclaimers regarding applicable federal law. Most of the activities of the Board and its employees in establishing and maintaining the web site would be considered discretionary, rather than ministerial, acts; the state is immune from liability for errors in discretionary acts under the California Tort Claims Act. An example of a potential ministerial error related to this bill would be the listing of an unapproved pharmacy in the place of an approved one on the website, or listing an approved pharmacy at the Internet address of an unapproved pharmacy, where the error resulted in the purchase of a drug that caused harm. A discretionary act would include deciding which Canadian pharmacies meet the standards this bill requires. The state would not be liable for making that decision in error because the decision making is a discretionary act.

6)CANADIAN SUPPLY ISSUES . In response to pressure from the Bush Administration, late in 2004 the Health Minister of Canada reversed his previous position that existing levels of sales to Americans posed no threat to the drug supply of Canada. Instead, the Health Minister and the Canadian government have begun to discuss the possibility of shutting down mail-order pharmacies. Although no action has been taken to date, in light of this threat to the supply of drugs sold to Americans, and in response to continuing efforts by drug manufacturers to restrict the supply of drugs into Canada, a number of states have examined whether their programs should link consumers to pharmacies in other countries besides Canada.

In the past year, representatives of the state of Illinois and of the state of Minnesota made separate visits to Europe to assess the quality of European pharmacies and pharmacists. Findings from these visits included: European pharmacist training is substantially equivalent to the US; pharmacy storage rules are similar; European distribution systems are similar to Canada (closed system with fewer opportunities for counterfeit drugs than in the U.S.); and European drug dispensing is safer and less prone to error (drugs are dispensed in manufacturer's precounted blister packs). In

October 2004, after receiving the results of his state's research on European importation, Illinois Governor Blagojevich launched the I-SaveRx program to provide access to Canadian, British and Irish pharmacies. Initially the program was open only to residents of Illinois and Wisconsin, but in recent months the states of Missouri, Kansas and Vermont have also joined. Minnesota Governor Pawlenty has yet to decide whether to expand the Minnesota RxConnect program, which links to Canada, to include European pharmacies.

Despite some narrowing of price differentials between the United States and Canada in the past year due to the weakening American dollar, consumers can still find substantial savings purchasing drugs from Canadian or British pharmacies. The author's office reports that a survey of prices of nine commonly prescribed medications listed on pharmacychecker.com on April 1, 2005, comparing costco.com prices with those available at Canadian and British pharmacies, revealed savings on a per pill basis of from 24 to 65% from the Canadian or British pharmacies.

7)SUPPORT . The California Medical Association, in support, argues that many patients are unable to follow a prescribed drug regime due to the high cost of prescription drugs and need the options this bill will provide. Other supporters argue that Californians are overburdened by overpriced drugs and need information on affordable and safe domestic and international sources of drugs. Supporters also argue that Democratic and Republican governors in other states have established websites for their residents to buy affordable drugs safely from other countries and that the time has come for California to join this nationwide effort.

8)OPPOSITION . Opponents argue that this bill puts consumer safety at risk, raises state liability concerns, and has a negative impact on biomedical research. The Pharmaceutical Research and Manufacturers of America (PhRMA) also argues that there are better and readily available programs to enable patients to access safe and affordable medicines. These include existing patient assistance programs which provided medicine to 244,000 Californians in 2002, a recently launched industry sponsored website, rxhelpforca.org, and the new Medicare prescription drug benefit that will go into full effect on January 1, 2006.

9)PREVIOUS LEGISLATION . AB 1957 (Frommer) of 2004, would have required DHS to establish a Web site to facilitate purchasing prescription drugs at reduced prices with links to Canadian pharmacies. SB 1149 (Ortiz) of 2004 would have required the Board of Pharmacy to establish a Web site to facilitate purchasing prescription drugs at reduced prices and would also

have included links to Canadian pharmacies. SB 1333 (Perata) of 2004 would have permitted DHS to reimburse pharmacies for drugs dispensed to Medi-Cal and AIDS Drug Assistance Program beneficiaries that are purchased from a Canadian pharmacy. AB 1957, SB 1149, and SB 1333 were all vetoed by the Governor, who stated that importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. However, in a formal legal opinion dated April 1, 2005, Legislative Counsel opined that the federal Food, Drug and Cosmetic Act would not have preempted the provisions of AB 1957 that would have established a prescription drug website with Canadian links.

10)RELATED LEGISLATION . AB 74 (Gordon) establishes the California Rx Prescription Drug Hotline to provide information about affordable prescription drug prices using a low-cost 1-900 telephone number.

11)DOUBLE REFERRAL . This bill has been double-referred. Should this bill pass out of this committee, it will be referred to the Assembly Business and Professions Committee.

REGISTERED SUPPORT / OPPOSITION :

Support

AIDS Healthcare Foundation
American Federation of State, County, and Municipal Employees
California Alliance of Retired Americans
California Federation of Teachers
California Labor Federation
California Medical Association
California Public Interest Research Group
California School Employees Association
California Teachers Association
City Council and City of Compton
Consumers Union
County of San Joaquin
Health Access California
Lieutenant Governor Cruz Bustamante
NAMI California
Older Women's League of California
Retired Public Employees Association
Senior Action Network
Service Employees International Union

Opposition

BIOCOM
California Chamber of Commerce
California Health Institute
Pharmaceutical Research and Manufacturers of America

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

AMENDED IN SENATE JUNE 23, 2005

AMENDED IN ASSEMBLY APRIL 20, 2005

AMENDED IN ASSEMBLY APRIL 6, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 74

Introduced by Assembly Members Gordon and Frommer (Coauthors: Assembly Members Chan, Chavez, Koretz, Laird, Matthews, Pavley, Ridley-Thomas, and Ruskin)
(Coauthor: Senator Alquist)

January 3, 2005

An act to add Article 5 (commencing with Section 110243) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 74, as amended, Gordon. California Rx Prescription Drug Hotline.

Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

This bill would require the department to establish the California Rx Prescription Drug Hotline, on or before July 1, 2006, to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices. The bill would establish a maximum cost per call to the hotline and require the hotline to provide specific information.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Prescription drugs have become essential for ensuring the health of millions of Californians.

(b) Increased spending on prescription drugs is a significant driver of increases in overall health care costs.

(c) Rising out-of-pocket costs for prescription drugs are placing a growing burden on California consumers, as federal government statistics show that in 2002 the increase in consumers' out-of-pocket costs for prescription drugs was greater than the increase in out-of-pocket costs for all other health care expenditures.

(d) The price of brand name drugs is rising faster than the rate of inflation, with a recent study showing that the price of 30 drugs most frequently used by the elderly rose by over four times the rate of inflation in 2003 and that some drugs increased in price by 10 times the rate of inflation in that period.

(e) The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford the medication they need to stay healthy.

(f) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

SEC. 2. Article 5 (commencing with Section 110243) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California Rx Precription Drug Hotline

110243. (a) The State Department of Health Services shall establish the California Rx Prescription Drug Hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

(b) The department shall establish a low-cost 1-900 telephone number on or before July 1, 2006. Callers shall be provided with

information about options for obtaining prescription drugs at affordable prices. The cost per call to the hotline shall not exceed 50 cents ($0.50) and the hotline shall, at a minimum, provide information about all of the following:

~~(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program and the Medicare Prescription Drug Discount and Transitional Assistance Program.~~

~~(2)~~

(1) State programs that provide drugs at discounted prices for California residents.

~~(3)~~

(2) Federal programs that provide drugs at discounted prices for United States residents.

~~(4)~~

(3) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

~~(5)~~

(4) Other informational resources as deemed appropriate by the department that help California residents to safely obtain prescription drugs at affordable prices, including, but not limited to, both of the following:

(A) Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government.

(B) Telephone numbers and *Internet* Web sites of health plans and health insurers regarding their prescription drug formularies.

~~(6)~~

(5) Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by all of the following:

(A) Licensed pharmacies in the state.

(B) Licensed pharmacies in other states.

(C) Pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.

(c) The department shall ensure that the hotline established pursuant to this section is coordinated with and does not

duplicate other state-funded programs and services, including, but not limited to, programs such as the Health Insurance Counseling and Advocacy Program (HICAP) established pursuant to Chapter 7.5 (commencing with Section 9540) of Division 8.5 of the Welfare and Institutions Code, that provide information about prescription drug options and costs.

(d) Any information provided via the hotline shall first be approved by professional staff of the department.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 74 **VERSION: AMENDED APRIL 20, 2005**

AUTHOR: GORDON **SPONSOR: GORDON**

RECOMMENDED POSITION:

SUBJECT: CALIFORNIA RX PRESCRIPTION DRUG HOTLINE

Existing Law:

The Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the California Department of Health Services (DHS). (H&S 109875)

This Bill:

1) Requires the DHS to establish the California Rx Prescription Drug Hotline (hotline) to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

2) Requires DHS to establish a low-cost 1-900 telephone number on or before July 1, 2006 and to limit the cost per call to the hotline to no more than 50 cents per call. The hotline would provide the following information:

a. State programs that provide drugs at discounted prices for California residents.

b. Federal programs that provide drugs at discounted prices for United States residents.

c. Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

d. Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government.

e. Telephone numbers and Web sites of health plans and health insurers regarding their prescription drug formularies.

f. Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by 1) licensed pharmacies in the state, 2) licensed pharmacies in other states, and 3) pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.

3) Requires that DHS ensure that the hotline is coordinated with and does not duplicate other state-funded programs and services , including, but not limited to, the Health Insurance Counseling and Advocacy Program (HICAP),, that provide information about prescription drug options and costs.

(H&S 1010243 Added)

Comment:

1) Author's Intent. The author's intent is to provide a one-stop-shop for information on how to obtain low priced prescription drugs. While much of this information is available on the Internet, the author is concerned that it's not getting to senior citizens, many of which who have never used a computer, let alone Internet.

As introduced, the measure would require DHS to establish a 1-900 telephone number for the program. The author is considering amending the bill to link the new program to an existing program and established 1-800 number. One option would be to link the program to the Health Insurance Counseling and Advocacy Program (HICAP), within California Department of Aging. HICAP assists individuals and families with Medicare problems and provides information on Medicare, Medicare supplement insurance, managed care, long-term care planning and health insurance.

2) Oversight. One of the many roles a pharmacist fills is acting as a second check for prescribers to insure that the medication a patient has been prescribed is the right medication for the patient's health condition, and that multiple medications will not adversely interact with each other to negatively effect a patient's health. As patients see specialist doctors for multiple health problems, the pharmacist's oversight role become increasingly more important, as any one doctor may not be aware of all the prescription drugs a patient is taking. Additionally, as patients seek lower cost drugs from more than one source (mail order, Internet, or local pharmacy), they will loose the benefit of one pharmacy or pharmacist knowing all the medications a patient is taking and ensuring that the medications will not result in harm to the patient. AB 74 and other bills that direct patients to multiple sources to obtain low cost drugs, may have the unintended result of putting peoples health at risk.

3) Drug Pricing. This bill requires DHS to provide price comparisons of commonly prescribed brand name prescription drugs, including typical prices charged by instate pharmacies, pharmacies in other states, and pharmacies in Canada. The problem with this requirement is it is impossible to come up with a "typical price charged" for a given drug. The true cost of a drug is influenced by factors including, but not limited to: discounts, rebates, and reimbursement formulas available to a particular purchaser, the number of manufacturers producing a given drug, and the supply and demand for a given drug in a given geographical area. In an effort to establish a benchmark for prescription drugs, standardized terms have been developed, however each term is limited in its ability to accurately establish the true price of prescription drugs. These terms include: average manufacturer price, average sales price, average wholesale price, federal supply schedule, and wholesale acquisition cost.

4) Substantive Amendments since the April 27th Board Meeting. Deletion of the provision that would require the hotline to provide information on prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program and the Medicare Prescription Drug Discount and Transitional Assistance Program.

6) History.

2005	
June 23	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
June 15	Referred to Com. on HEALTH.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 47. Noes 31. Page 2104.)
May 27	Read second time. To third reading.
May 26	From committee: Do pass. (Ayes 12. Noes 5.) (May 25).
May 4	In committee: Set, first hearing. Referred to APPR. suspense file.
Apr. 27	From committee: Do pass, and re-refer to Com. on APPR.Re-referred. (Ayes 7. Noes 1.) (April 26).
Apr. 21	Re-referred to Com. on B. & P.

Apr. 20	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 10. Noes 4.) (April 12).
Apr. 7	Re-referred to Com. on HEALTH.
Apr. 6	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

AB 74

As Amended: June 23, 2005

SENATE HEALTH

COMMITTEE ANALYSIS
Senator Deborah V. Ortiz, Chair

FISCAL: Appropriations
4

CONSULTANT:
Bohannon / ak

SUBJECT

California Rx Prescription Drug Hotline

SUMMARY

This bill would require the Department of Health Services (DHS) to establish the California Rx Prescription Drug Hotline (hotline), on or before July 1, 2006, to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

ABSTRACT

Existing law:

1. Establishes the Sherman, Food, Drug, and Cosmetics Act to regulate the processing, packaging, labeling, advertising, and sale of food, drugs, devices, and cosmetics under the administration of DHS.

2. Expresses the intent of the Legislative to ensure that older individuals and functionally impaired adults receive needed services that will enable them to maintain maximum independence and remain in their home or communities for as long as possible.

3. Declares that the purpose of the Health Insurance Counseling and Advocacy Program (HICAP) is to provide Medicare beneficiaries and those imminent of becoming eligible for Medicare with counseling and advocacy as to Medicare, private health insurance, and related health care coverage plans, on a statewide basis.

4. Requires the California Department of Aging (CDA) to be responsible for acting as a clearinghouse for information

and materials relating to Medicare, managed care, health and long-term care related life and disability insurance, and related health care coverage plans and to develop additional information and materials as necessary.

This bill:

1. Makes the following legislative findings and declarations:

   Prescription drugs have become essential for ensuring the health of millions of Californians;

   Increased spending on prescription drugs is a significant driver of increases in overall health care costs;

   Rising out-of-pocket costs for prescription drugs are placing a growing burden on California consumers;

   The price of brand name drugs is rising faster than the rate of inflation;

   The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford the medication they need to stay healthy; and,

   California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

1. Requires DHS to establish the hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

2. Requires DHS to establish a low-cost 1-900 telephone number on or before July 1, 2006.

3. Requires the cost per call to the hotline not to exceed 50 cents and at a minimum, provide information about all of the following:

   State programs that provide drugs at discount prices for California residents;

   Federal programs that provide drugs at discount prices for United States residents;

   Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription

drugs to qualifying individuals;

Other informational resources as deemed appropriate by DHS that help California residents to safely obtain prescription drugs at affordable prices, including, but not limited to, both of the following:

a. Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government;

b. Telephone numbers and Internet Web sites of health plans and health insurers regarding their prescription drug formularies.

Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by licensed pharmacies in California and in other states as well as those charged by Canadian pharmacies that are licensed by the state and federal government.

1.Requires DHS to ensure that the hotline is coordinated with and does not duplicate other state-funded programs and services, including, but not limited to, programs such as the HICAP that provide information about prescription drug options and costs.

2.Requires any information provided via the hotline to first be approved by professional staff of the department.

FISCAL IMPACT

According to the Assembly Appropriations Committee, there will be full-year General Fund (GF) costs of approximately $800,000 to establish and maintain the database to support the hotline, including keeping the hotline message current, establishing and keeping prescription price comparison information, and responding to hotline inquiries. Additionally, there are indeterminate, but potentially significant GF costs to establish and maintain the "900" service, depending upon the number of calls to the hotline.

BACKGROUND AND DISCUSSION

Purpose of bill
According to the author, there are a multitude of programs and services offered by a variety of sources that can

provide eligible seniors with immediate relief from high prescription drug costs. The author argues that few seniors take advantage of these benefits because they are not aware that such programs exist or are either deterred by complex enrollment processes. He insists that studies show that only 40 percent of seniors have ever used a computer and even less have ever gone online to access information on the Internet. As such, he believes AB 74 is needed to provide Californians, especially seniors, with a non-web based alternative for finding affordable prescription drugs. He believes the measure will provide the support necessary to help Californians navigate the complicated web of services for which they might be eligible.

Rising prescription drug costs

As a number of studies document, access to affordable prescription drugs is a growing problem in California and in the U.S. According to the Kaiser Family Foundation (KFF), almost a quarter of Americans under age 65 have no prescription drug coverage. In California, according to the UCLA Center for Health Policy Research, nearly one in five Californians under age 65 lacked health coverage altogether in 2001, a substantial percentage of whom are not eligible for most public assistance or drug assistance programs due to excess income or assets. Of those who do have health coverage, over 2 million report that they do not have coverage for prescription drugs.

Further, prescription drugs represent one of the fastest growing health care expenditures as drug prices continue to grow at roughly twice the rate of inflation in California and the rest of the U.S. Of the 50 drugs used most frequently by seniors, the average annual cost as of January 2003 was $1,439. The five most frequently prescribed medications for the elderly all had annual costs of between $500 and $1,500 per year. According to surveys, substantial percentages of seniors forego taking their medications due to the high cost.

Seniors and the Internet

A report released by the KFF in January 2005 found that there is a substantial digital divide among seniors based on income, education, age, and gender. According to KFF, seniors whose annual household income was under $20,000 a year were much less likely to have gone online than those with incomes between $20,000 and $49,000 or those with incomes of $50,000 a year or more. However, most seniors fall into the lower income category - 64% of all seniors on Medicare have an annual income under $20,000 a year, while just 8% have an income of $50,000 a year or more.

Additionally, the report found that while the Internet is a source of health information for some seniors, the vast majority still rely on traditional media such as television and newspapers to obtain health information. However, of those seniors who do utilize the Internet for health information, KFF found that most are looking for information on prescriptions drugs.

1-800-MEDICARE

In March 1999, the Center for Medicare and Medicaid Services (CMS) implemented a nationwide toll-free telephone helpline, 1-800-MEDICARE, which Medicare beneficiaries, their families, and other members of the public can call to ask questions about program eligibility, enrollment, and benefits. By 2001, the helpline had customer service representatives (CSR) answering calls 24 hours a day, seven days a week.

In 2004, the helpline significantly expanded its operations in order to handle an increased number of calls. During the six months following the enactment of the Medicare Prescription Drug Improvement and Modernization of 2003 (MMA), the 1-800-MEDICARE helpline handled over nine million calls, more than triple the number handled in the previous six months. In response to the increased call volume, in the first half of 2004, CMS added over 800 CSRs, more than doubling the number of staff who had previously been available to respond to helpline inquiries.

In December 2004, the United States Government Accountability Office (GAO) released a report evaluating accuracy of responses from the 1-800-MEDICARE helpline. Among other things, the report found that the accuracy rate varied significantly by question and that inaccurate responses were largely due to ineffective use of call scripts. The report concluded that although the CSRs had met CMS's training requirements, such training was not sufficient to ensure accurate responses to beneficiary inquiries.

HICAP

The HICAP program, under the purview of CDA, is charged with providing assistance to and advocacy for individuals and families for problems with Medicare and other health insurance related concerns. Over 600 trained and registered volunteer counselors provide objective information on Medicare (including Medicare Part D - the voluntary outpatient prescription drug benefit available January 1, 2006), Medicare supplement insurance, managed care, long-term care planning and health insurance.

Community education, individual counseling and some legal services are available in all 58 counties. HICAP counselors can be reached via toll free number (1-800-434-0222) for appointments and questions.

Arguments in support

Supporters of the bill believe AB 74 will assist consumers, especially those without Internet access, to find affordable prescription drugs. They believe the state is the proper administrator for such a program since it has access to information and research that ordinary consumers do not. Supporters state that existing information about international pharmacies and various government and private assistance programs is notoriously unreliable and difficult to navigate. They believe AB 74 will facilitate access to information that will allow consumers to obtain the preventative medication they need to avoid more complicated and expensive emergency procedures.

Arguments in opposition
DHS argues that AB 74's proposed low-cost hotline will frustrate, not alleviate, a patient's ability to receive appropriate prescription drug information. DHS also believes the bill's requirements are unnecessary and duplicate other hotlines that are already available. DHS additionally insists that compliance with providing price comparison information on at least 50 commonly prescribed drugs, as required by AB 74, would be difficult as such a comparison assumes that information is readily available, accurate, and based on the same quantity per prescription. Lastly, DHS argues that requiring the hotline to provide other information, including the availability of prescriptions from Canadian pharmacies, would establish a mechanism to facilitate an illegal practice and possibly jeopardize patient safety.

Related legislation
AB 73 (Frommer, 2005) would require DHS to establish a Web site on or before July 1, 2006, to provide information to California residents about options for obtaining prescription drugs at affordable prices, including information about and electronic links to certain federal, state, and private pharmaceutical programs, pharmacies located in Canada, the United Kingdom, and Ireland that meet specified requirements, and other web sites. This bill has been referred to the Senate Business, Professions and Economic Development Committee.

1.Low cost may be a deterrent for low-income. AB 74

requires the cost per call not to exceed 50 cents. However, as DHS asserts, if callers are not prepared with paper and pencil, they may need to call again, causing them to incur additional charges. As stated earlier in the analysis, 64% of all seniors on Medicare have an annual income under $20,000 a year, while just 8% have an income of $50,000 a year or more. Additionally, many of those who would qualify for the public and private pharmaceutical assistance programs specified in the bill are low income as well, with income between 100% and 300% of the federal poverty level to qualify for most programs. While the 50 cent fee may help offset some of the administrative costs associated with the program, it may have the unintended consequence of serving as a deterrent for some or an additional financial hardship for others in some cases.

2. Administrative details are unclear. Does the author intend for the hotline created pursuant to AB 74 to be automated or operator run? Automated phone trees can be frustrating and confusing particularly when callers are unfamiliar with the options presented to them. Further, as evidenced by the CSRs staffing the 1-800-MEDICARE helpline, training and additional support materials (i.e. call scripts) for live operators still may not prevent callers from receiving misleading or inaccurate information.

3. Linguistic competency standards. AB 74 does not provide for the appropriate linguistic competency and technological support services necessary to ensure the hotline is accessible to California's diverse population, including those who may be hearing-impaired.

4. Lack of outreach. The bill does not require DHS to conduct outreach to publicize the hotline. While potentially very costly, particularly for low-income populations, outreach is a vital component to the success of any program which requires participants to actively engage in a specified activity in order to receive information or services.

5. Inherent duplication may be inevitable and ultimately confusing. While the bill expressly requires DHS to ensure that the hotline established pursuant to AB 74 does not duplicate any other state-funded programs and services, inherent duplication may be inevitable not only among other state-funded programs and services, but among those funded by federal and private dollars as well. Many of those who call the hotline will undoubtedly be Medicare beneficiaries who are eligible for the

low-income subsidy under Medicare Part D, as they would also qualify for many of the programs AB 74 seeks to centralize via hotline. Amendments taken on June 23, 2005 removed language that would have required the hotline to provide information regarding prescription drug benefits available to Medicare beneficiaries. While the information required by the bill may be useful to this population, they would undoubtedly fair better under the new drug benefit, however the bill provides no avenue for these individuals to access this information should they call the hotline first. Should the bill be amended to require the hotline to provide referral service to HICAP for the purposes of informing callers about prescription drug benefits available to Medicare beneficiaries?

6. Is AB 74 well intentioned, but impractical? Prescription drug pricing and discount programs are increasingly difficult to understand and maneuver given complicated eligibility requirements which may vary depending on the program or drug. Arguably a centralized hub of information that is accessible by telephone may be beneficial in terms of informing patients that these programs actually exist, particularly for seniors who are not as comfortable using the Internet. However if individuals are not prepared to properly record the information they receive or lack the resources and assistance to proactively apply for assistance after they call, it is unclear what tangible benefit the hotline would realistically provide.

PRIOR ACTIONS

Assembly Floor: 47 - 31 Pass
Assembly Appropriations: 12 - 5 Do Pass
Assembly Bus. & Prof.: 7 - 1 Do Pass
Assembly Health: 10 - 4 Do Pass

POSITIONS

Support: AFSCME
AIDS Healthcare Foundation
California Federation of Teachers
California Medical Association
California Nurses Association
California School Employees Association
California State Employees Association
California Teachers Association
CALPIRG
Gray Panthers
Greenlining Institute

Health Access
Mental Health Association in California
NAMI California
Independent Employees of Merced County
Protection and Advocacy
Retired Public Employees Association
San Bernardino Public Employees Association
San Joaquin County

SEIU

Oppose: Department of Health Services

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY MAY 2, 2005

AMENDED IN ASSEMBLY APRIL 19, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 75

Introduced by Assembly Members Frommer and Chan
(Principal coauthor: Assembly Member Baca)
(Coauthors: Assembly Members Bass, Berg, Cohn, Coto, De La Torre, Evans, Goldberg, Gordon, Hancock, Klehs, Koretz, Leno, Levine, Lieber, Nava, Pavley, Ridley-Thomas, Ruskin, Saldana, ~~and Salinas~~ *Salinas, and Torrico*)
(Coauthor: Senator Alquist)

January 3, 2005

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 75, as amended, Frommer. Pharmaceutical assistance program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Plus State Pharmacy Assistance Program, to be administered by the department. The bill would authorize the department to negotiate drug rebate agreements

with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under the program. The bill would establish eligibility criteria and application procedures for California residents to participate in the program. The bill would make it a misdemeanor for a person to intentionally make false declarations as to his or her eligibility or eligibility on behalf of any other person seeking eligibility. Because this bill would create a new crime, it would impose a state-mandated local program.

The bill would establish the California Rx Plus Program Fund, into which all payments received under the program would be deposited, with this fund to be used for the purpose of implementing the program, upon appropriation by the Legislature.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Division 112 (commencing with Section 130500) is added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA RX PLUS STATE PHARMACY ASSISTANCE PROGRAM

CHAPTER 1. GENERAL PROVISIONS

130500. (a) This division shall be known, and may be cited, as the California Rx Plus State Pharmacy Assistance Program.

(b) For purposes of this division, the following definitions apply:

(1) "Department" means the State Department of Health Services.

(2) "Fund" means the California Rx Plus Program Fund.

(3) "Manufacturer" means a drug manufacturer, as defined in Section 4033 of the Business and Professions Code.

(4) "Program" means the California Rx Plus State Pharmacy Assistance Program.

(5) (A) "Qualified resident" means a resident of California who has a *gross* family income equal to or less than 400 percent of the federal poverty guidelines, as updated periodically in the Federal Register by the United States Department of Health and Human Services under the authority of Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902(2)).

(B) "Qualified resident" also means a resident of the state whose family incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of *gross* family income or whose total unreimbursed medical expenses equal 15 percent or more of *gross* family income.

(C) For purposes of this paragraph, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.

(6) "Resident" means a resident of California pursuant to Section 17014 of the Revenue and Taxation Code.

130501. There is hereby established in the State Department of Health Services, the California Rx Plus State Pharmacy Assistance Program.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCEDURES

130505. (a) To be eligible for the program, a person shall be a qualified resident, as defined in paragraph (4) of subdivision (b) of Section 130500 and shall not have outpatient prescription drug coverage paid for in whole or in part by the Medi-Cal program or the Healthy Families Program, or any other program that uses federal funds to pay part or all of the cost of the person's outpatient prescription drugs.

(b) Notwithstanding subdivision (a), a person enrolled in Medicare may participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare.

130506. (a) The department shall establish application forms and procedures for enrollment in the program. The application form shall include a requirement that the applicant or the

applicant's guardian or custodian attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(b) In assessing the income requirement for program eligibility, the department shall use the income information reported on the application and shall not require additional documentation.

(c) Any person who intentionally makes a false declaration as to his or her eligibility or any person who intentionally makes a false declaration as to eligibility on behalf of any other person seeking eligibility under this division for which that person is not eligible shall be guilty of a misdemeanor.

(d) Any person who intentionally makes a false declaration as to his or her eligibility or any person who intentionally makes a false declaration as to eligibility on behalf of any other person seeking eligibility under this division for which that person is not eligible may be denied a drug discount card under this program for up to one year from the date of the denial of coverage by the department.

(e) Upon determination of eligibility, the department shall mail the qualified resident a California Rx Plus Discount Card.

130507. (a) The department shall execute agreements with drug manufacturer patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs.

(b) The department shall develop a system to provide a participant under this division with the best discounts on prescription drugs that are available to the participant through this program or through a drug manufacturer patient assistance program.

(c) (1) The department may require an applicant to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.

(2) The department shall not require an applicant to participate in a drug manufacturer patient assistance program or to disclose information that would determine the applicant's eligibility to participate in a drug manufacturer patient assistance program in order to participate in the program established pursuant to this division.

(d) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the department shall require drug manufacturers to provide the department annually with all of the following information:

(1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(2) The total number of prescriptions or 30-day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(3) The total number of prescriptions or 30-day supplies, and total value, of each of the manufacturer's brand name drugs provided at no or very low cost to California residents during the previous year.

(e) The California Rx Plus Discount Card issued pursuant to subdivision (e) of Section 130506 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130515. (a) The department shall conduct an outreach program to inform California residents of their opportunity to participate in the California Rx Plus State Pharmacy Assistance Program. The department shall implement an outreach, education, and enrollment program with Health Insurance Counseling and Advocacy Program agencies, the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program.

(b) The department shall implement a plan to prevent the occurrence of fraud in the program.

130516. (a) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program.

(b) Any drug manufacturer may participate in the program.

130517. (a) The amount a program participant pays for a drug through the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the

specific drug or an average discount for a group of drugs or all drugs covered by the program.

(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the drug's manufacturer and the state's share of the discount.

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

130518. (a) The department shall negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program.

(b) The department shall seek to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medi-Cal rebate program pursuant to Section 14105.33 of the Welfare and Institutions Code.

(c) Upon receipt of a determination from the federal Centers for Medicare and Medicaid Services that the program is a state pharmaceutical assistance program as provided in Section 130522, the department shall seek to contract for drug rebates that result in a net price lower than the Medicaid best price for drugs covered by the program.

(d) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.

(e) All of the drug rebates negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by participants in the program.

(f) Each drug rebate agreement shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

(6) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(7) Require the manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).

(8) Require the manufacturer to calculate and pay interest on late or unpaid rebates. The department may, by regulation, establish the date upon which the interest payments by drug manufacturers shall begin to accrue as well as any other regulations it deems necessary for the implementation of this paragraph.

(g) The department may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in the drug rebate agreements executed pursuant to this section.

130519. (a) (1) The department may require prior authorization in the Medi-Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) for any drug of a manufacturer that does not agree to provide rebates to the department for prescription drugs purchased under this division, to the extent the department determines *that* it is appropriate to do *so* in order to encourage manufacturer participation in the program, ~~and~~ to the extent permitted by federal law, and subject to any necessary federal approvals or waivers.

(2) In making a determination to require prior authorization in the Medi-Cal program pursuant to paragraph (1), the department shall ensure that there are as many single-source drugs within each therapeutic category or subcategory as the department determines necessary to meet the health needs of the Medi-Cal population. In no event shall a Medi-Cal beneficiary be denied continued use of a drug that is part of a prescribed therapy unless that drug is no longer prescribed for that beneficiary.

(b) The names of manufacturers that do and do not enter into rebate agreements with the department pursuant to this division shall be public information and shall be released to the public.

130520. Contracts entered into for purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. Contracts with

pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

130522. The department shall seek a determination from the federal Centers for Medicare and Medicaid Services that the program established pursuant to this division complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) and that discounts provided under the program are exempt from the Medicaid best price requirement.

130523. (a) The department shall deposit all payments the department receives pursuant to this division into the California Rx Plus Program Fund, which is hereby established in the State Treasury.

(b) Upon appropriation by the Legislature, moneys in the fund shall be used for the purpose of providing payment to participating pharmacies pursuant to Section 130517 and for defraying the costs of administering this division. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

(c) Notwithstanding Section 16305.7 of the Government Code, the fund shall also contain any interest accrued on moneys in the fund.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 75 **VERSION: AMENDED MAY 26, 2005**

AUTHOR: FROMMER **SPONSOR: FROMMER**

RECOMMENDED POSITION:

SUBJECT: PHARMACEUTICAL ASSISTANCE PROGRAM

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1. Establishes the California Rx Plus State Pharmacy Assistance Program (Program) within DHS. (H&S 130501 Added)

2. Defines the terms: Program, Department (DHS), fund (California Rx Plus Program Fund), program, manufacturer (drug manufacturer), resident, and qualified resident. (H&S 130500 Added)

3. Establishes the criteria for a qualified resident as:

   a. A resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines. (2005 - $38,280 for an individual and $77,400 for a family of four)

   b. A family that incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of family income or whose total unreimbursed medical expenses equal fifteen percent or more of family income. (H&S 130500 Added)

4. Allows an individual enrolled in Medicare to participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare. (H&S 130505 Added)

5. Requires DHS to conduct an outreach program to inform California residents of their opportunity to participate in program. Requires DHS to coordinate outreach activities with the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program. (H&S 130515 Added)

6. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program and to seek rebates equal to or greater then Medi-Cal rebates. (H&S 130518 Added)

7. Requires that all of the drug rebates negotiated will be used to reduce the cost of drugs purchased by participants in the program. (H&S 130518 Added)

8. Establishes the California Rx Plus Program Fund, but does not appropriate funds to implement the program. (H&S 130523 Added)

9. Makes it a misdemeanor to falsify information to gain access to the program. Additionally, it bars a person for one year from the program if the person falsifies information to gain access to the program. (H&S 130506 Added)

Comment:

1) Author's Intent. The author is concerned about the high cost of prescription drugs and the inability of uninsured individuals to pay for their medications.

2) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty- five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

3) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

4) Related Legislation.

SB 19 (Ortiz) California Rx Program. This bill is sponsored by the Governor and would establish a state program to negotiate for lower price prescription drugs for lower income Californians. SB 19 failed to make it out of the Senate and is now a two-year bill.

5) Support / Opposition.

Support: AIDS Healthcare Foundation
Alzheimer's Association
American Federation of State, County and Municipal Employees
California Alliance for Retired Americans
California Federation of Labor
California Federation of Teachers
California Labor Federation
California Nurses Association
California Pharmacists Association
California Public Interest Research Group
Consumers Union
Health Access California
NAMI California (if amended)
Older Women's League of California
Retired Public Employees Association
Senior Action Network
Service Employees International Union

Opposition: BIOCOM
California Chamber of Commerce
Department of Health Services (unless amended)
National Association of Chain Drug Stores (unless amended)
Mental Health Association of California
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America
Western Center on Law & Poverty
Wyeth Pharmaceuticals

6) History.

2005

June 28	In committee: Set, first hearing. Hearing canceled at the request of author.
June 15	Referred to Com. on HEALTH.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 43. Noes 34. Page 2141.)
May 27	Read second time. To third reading.
May 26	From committee: Amend, and do pass as amended. (Ayes 11. Noes 4.) (May 25). Read second time and amended. Ordered returned to second reading.
May 11	In committee: Set, first hearing. Referred to APPR. suspense file.
May 3	Re-referred to Com. on APPR.
May 2	Read second time and amended.
Apr. 28	From committee: Amend, and do pass as amended, and re-refer to Com. on APPR. (Ayes 7. Noes 1.) (April 26).
Apr. 20	Re-referred to Com. on B. & P.
Apr. 19	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 9. Noes 2.) (April 12).
Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

AB 75

As Amended May 26, 2005

ASSEMBLY THIRD READING

HEALTH	9-2	BUSINESS & PROFESSIONS	7-1

Ayes:	Chan, Cohn, Dymally, Frommer, De La Torre, Jones, Montanez, Negrete McLeod, Ridley-Thomas	Ayes:	Negrete McLeod, Bass, Frommer, Koretz, Nation, Vargas, Yee
Nays:	Aghazarian, Strickland	Nays:	Maze

APPROPRIATIONS	11-4		

Ayes:	Chu, Bass, Berg, Karnette, Klehs, Leno, Nation, Oropeza, Ridley-Thomas, Saldana, Yee		
Nays:	Sharon Runner, Emmerson, Haynes, Walters		

SUMMARY : Establishes the California Rx Plus State Pharmacy Assistance Program (Program), to be administered by the Department of Health Services (DHS). Specifically, this bill :

1)Authorizes DHS to negotiate drug rebate agreements with drug manufacturers.

2)Limits Program eligibility to qualified residents of California who do not have outpatient prescription drug coverage under any program funded in whole or part by the federal government except that a qualified resident enrolled in Medicare may participate in the program to the extent allowed by federal law.

3)Defines "qualified resident" to mean either of the following:

a) A resident of California who has a family income equal to or less than 400% of the federal poverty guidelines (FPL); or,

b) A resident of the state whose family incurs unreimbursed expenses for prescription drugs that equal 5% or more of family income or whose total unreimbursed medical expenses equal 15% or more of family income.

4)Requires DHS to execute agreements with drug manufacturer patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs.

5)Requires DHS to develop a system, as specified, to provide a Program participant with the best discounts on prescription drugs that are available to the participant through the Program or through a drug manufacturer patient assistance program.

6)Requires drug manufacturers to report annually to DHS regarding the utilization of drug company assistance programs.

7)Requires DHS to conduct an outreach program to inform California residents of their opportunity to participate in the Program.

8)Requires the amount a participant pays for a drug through the Program to be equal to the participating pharmacies usual and customary charge, or contract rate as specified, less a Program discount, as specified.

9)Requires DHS to negotiate drug rebate agreements with drug manufacturers and to seek rebate amounts equal to or greater than the Medi-Cal rebate, as specified. Requires various provisions in rebate agreements.

10) Permits DHS to limit the number of drugs available through the Program to obtain the most favorable discounts.

11) Requires all drug rebates negotiated pursuant to this bill to be used to reduce the cost of drugs purchased by Program participants.

12) Permits DHS to require Medi-Cal prior authorization for any drug of a manufacturer that does not agree to provide rebates to the Program. Requires DHS, in making the determination to require prior authorization in the Medi-Cal program, to ensure that there are as many single-source drugs within each drug therapeutic category or subcategory as DHS

determines necessary to meet the health needs of the Medi-Cal population. Prohibits a Medi-Cal beneficiary from being denied continued use of a drug that is part of a prescribed therapy unless that drug is no longer prescribed for that beneficiary.

13) Requires the names of manufacturers that do and do not agree to Program rebates to be public information.

14) Exempts Program contracts from the Public Records Act.

15) Requires DHS to seek a determination from the federal Centers for Medicare and Medicaid Services that the Program established pursuant to this bill complies with the requirements for a state pharmaceutical assistance program and that discounts provided under the Program are exempt from the Medicaid best price requirement.

16) Requires DHS to deposit all payments received pursuant to this bill into the California Rx Plus Program Fund (Fund) to be established in the State Treasury. Requires the moneys in the Fund to be used to pay participating pharmacies and to defray costs of administering the provisions of this bill.

FISCAL EFFECT : According to the Assembly Appropriations Committee analysis:

1)Based on funding in the Governor's fiscal year 2005-06 Budget for his similar proposal, general Fund (GF) costs of $3.9 million for Program staff and administrative costs. Unknown costs, likely one-time in nature and dependent upon enrollment, associated with the delayed receipt of rebates and initial payments to pharmacies.

2)On-going state costs, potentially in the millions to low tens of millions of dollars annually, for outreach activities to implement the new drug discount program.

3)Unknown foregone revenue from Medi-Cal supplemental rebates if drug manufacturers fail to provide rebates under this bill and their drugs are removed from the Medi-Cal preferred drug list. The state currently projects receiving $322 million (GF) in supplemental Medi-Cal rebates in 2005-06.

4)Unknown savings on state and county health program costs due to the availability of drug discounts.

COMMENTS : According to the author, this bill is needed to help Californians cope with the rising cost of prescription drugs by creating a drug discount card program for state residents. The author states that despite the skyrocketing cost of drugs, to

date the state has done little, compared to other states, to help residents afford their medication.

State Pharmacy Assistance Programs (SPAPs) are state-sponsored programs that generally provide selected populations with increased access to prescription drugs. As of March 2005 at least 39 states had established or authorized some type of program, to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Currently, 32 state programs are in operation. Most programs utilize state funds to subsidize a portion of an individual's drug costs, but an increasing number use discounts or bulk purchasing approaches.

Though most SPAPs target low-income individuals who are not eligible for Medicaid, many states have expanded their programs to serve individuals with higher incomes as well. All states provide coverage to those aged 65 and older, and half of the programs cover individuals with disabilities under age 65. Eligibility levels range from 100% FPL ($9,310 for an individual in 2004) in Arkansas and Louisiana to 500% FPL in Massachusetts ($46,550 for an individual in 2004). A few states have moved toward offering the benefits regardless of income, adjusting cost sharing requirements accordingly. In addition, a few programs have adjusted eligibility limits for individuals who have prescription drug expenses that are considered "catastrophic" (ranging from 3% to 40% of income).

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

FN: 0010841

AMENDED IN SENATE JUNE 22, 2005

AMENDED IN ASSEMBLY MAY 2, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 76

Introduced by Assembly Members Frommer and Chan
(Coauthors: Assembly Members Baca, Bass, Berg, Cohn, Coto, De La Torre, Evans, Goldberg, Gordon, Hancock, Klehs, Koretz, Leno, Levine, Lieber, Nava, Pavley, Ridley-Thomas, Ruskin, Saldana, and Torrico)
(Coauthor: Senator Alquist)

January 3, 2005

An act to amend Section 12803 of, to add Part 5.4 (commencing with Section 14570) to, and to repeal Chapter 12 (commencing with Section 14977) of Part 5.5 of, Division 3 of Title 1 of, the Government Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 76, as amended, Frommer. Office of Pharmaceutical Purchasing.

Existing law authorizes the Department of General Services to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. Existing law requires 4 state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. Existing law grants the Department of General Services

authority with respect to contracting with a pharmaceutical benefits manager or other entity and exploring additional strategies for managing drug costs.

This bill would repeal these provisions. The bill would instead establish within the California Health and Human Services Agency the Office of Pharmaceutical Purchasing with authority and duties to purchase prescription drugs for state agencies similar to that granted to the Department of General Services under the above-described provisions. The bill would also, however, require the office to be the purchasing agent for the California State University and any other state agency as directed by the Governor, would add to those entities that may elect to participate in the purchasing program, and would authorize the office to conduct specified activities in order to negotiate the lowest prices possible for prescription drugs. ~~The bill would require the office, on or before February 1, 2007, and annually thereafter, to submit a report containing specified information to certain committees of the Legislature regarding the program.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 12803 of the Government Code is amended to read:

12803. (a) The California Health and Human Services Agency consists of the following departments: Health Services; Mental Health; Developmental Services; Social Services; Alcohol and Drug Abuse; Aging; Rehabilitation; and Community Services and Development.

(b) The agency also includes the Office of Statewide Health Planning and Development and the State Council on Developmental Disabilities.

(c) The Department of Child Support Services is hereby created within the agency commencing January 1, 2000, and shall be the single organizational unit designated as the state's Title IV-D agency with the responsibility for administering the state plan and providing services relating to the establishment of paternity or the establishment, modification, or enforcement of child support obligations as required by Section 654 of Title 42 of the United States Code. State plan functions shall be

performed by other agencies as required by law, by delegation of the department, or by cooperative agreements.

(d) The Office of Pharmaceutical Purchasing is hereby established within the agency and shall purchase prescription drugs for state agencies pursuant to Part 5.4 (commencing with Section 14570).

SEC. 2. Part 5.4 (commencing with Section 14570) is added to Division 3 of Title 1 of the Government Code, to read:

PART 5.4. OFFICE OF PHARMACEUTICAL PURCHASING

14570. As used in this part, "office" means the Office of Pharmaceutical Purchasing within the California Health and Human Services Agency.

14571. (a) Notwithstanding any other provision of law, the office may enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. The office may obtain from those manufacturers and suppliers, discounts, rebates, or refunds based on quantities purchased insofar, as permissible under federal law. Contracts entered into pursuant to this part may include price discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices.

(b) Contracts under this part shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

~~(c) The State Department of Health Services may require prior authorization in the Medi-Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) for any drug of a manufacturer that does not agree to provide rebates to the office for prescription drugs purchased under this part to the extent the department determines it is appropriate to do so in order to encourage manufacturer participation, and to the extent permitted by federal law and subject to any necessary federal approvals or waivers. In making the determination to require prior authorization in the Medi-Cal program under this subdivision, the department shall ensure that there are as many single-source drugs within each drug therapeutic category or subcategory as the department determines necessary to meet the health needs of the Medi-Cal population. In no event shall a~~

~~Medi-Cal beneficiary be denied continued use of a drug that is part of a prescribed therapy unless that drug is no longer prescribed for that beneficiary. It is the intent of the Legislature to limit any rebates that are obtained as a result of the establishment of a prior authorization requirement in Medi-Cal to drugs prescribed to financially needy individuals who, through the use of these prescribed drugs, would improve their health status and become less likely to enroll in the Medi-Cal program.~~

14572. (a) The office shall be the purchasing agent for prescription drugs for all of the following state entities:

(1) Department of Corrections.

(2) State Department of Mental Health.

(3) Department of the Youth Authority.

(4) State Department of Developmental Services.

(5) California State University.

(6) Any other state agency as directed by the Governor.

(b) Any state, district, county, city, municipal, school district, joint powers agreement or trust that administers or pays public employee benefits, or public agency governmental entity, other than a state entity specified in subdivision (a), may elect to participate in the coordinated purchasing program.

14573. (a) ~~The office shall work with the University of California to identify opportunities for consolidating the drug purchases made by both agencies in order to lower the state's costs for purchasing prescription drugs. It is the intent of the Legislature that the University of California cooperate with the office in these efforts.~~ *It is the intent of the Legislature that the office, the University of California, and the Public Employees' Retirement System regularly meet and share information regarding each agency's procurement of prescription drugs in an effort to identify and implement opportunities for cost savings in connection with this procurement. It is the intent of the Legislature that the University of California and the Public Employees' Retirement System cooperate with the office in order to reduce each agency's costs for prescription drugs.*

~~(b) The office shall develop an annual workplan that provides a comprehensive approach to reducing the state's procurement costs for prescription drugs. The workplan shall detail the office's annual activities and the estimated savings that these activities are expected to achieve. The office shall use the~~

~~workplan when reporting to the Legislature on estimated and achieved savings resulting from the office's activities.~~

~~(c) The office shall participate in at least one independent group that develops information on the relative effectiveness of prescription drugs.~~

~~(d) (1) It is the intent of the Legislature that the state provide parolee medications in the most cost-effective manner. In deciding how to purchase parolee medications, the office shall consider, but not be limited to, all of the following:~~

~~(A) Contracting with a pharmacy benefits manager.~~

~~(B) Purchasing medications under pharmacy contracts used for prison inmates.~~

~~(C) To the extent feasible, requiring prior authorization in the Medi-Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) to obtain drug discounts for the parolee population.~~

~~(2) The office shall compare the cost of these options and choose the lowest cost option.~~

(b) The office shall do all of the following:

(1) Share information on a regular basis with the University of California and the Public Employees' Retirement System regarding each agency's procurement of prescription drugs, including, but not limited to, prices paid for the same or similar drugs and information regarding drug effectiveness.

(2) Identify opportunities for the office, the University of California, and the Public Employees' Retirement System to consolidate drug procurement or engage in other joint activities that will result in cost savings in the procurement of prescription drugs.

(3) Participate in at least one independent association that develops information on the relative effectiveness of prescription drugs.

(4) No later than January 1, 2007, and annually thereafter, develop a work plan that includes, but is not limited to, a description of the office's annual activities to reduce the state's costs for prescription drugs and an estimate of cost savings.

(5) No later than January 10, 2007, and annually thereafter, report to the chairperson of the Joint Legislative Budget Committee and the chairs of the fiscal committees of the Legislature on any joint activities of the office, the University of

California, and the Public Employees' Retirement System in the last 12 months in connection with procurement of prescription drugs and any resulting cost savings. This report shall include the work plan prescribed in paragraph (4).

(c) Nothing in this section shall be construed to require sharing of information that is prohibited by any other provision of law or contractual agreement, or the disclosure of information that may adversely effect potential drug procurement by any state agency.

14574. (a) In order to negotiate the lowest prices possible for prescription drugs for purposes of this part, the office may do all of the following:

(1) Establish a formulary or formularies for state programs in consultation with the affected agencies.

(2) Pursue all opportunities for the state to achieve savings through the federal 340B program, as established under Section 340B of the Public Health Service Act (42 U.S.C. Sec. 256b), including the development of cooperative agreements with entities covered under the 340B program that increase access to 340B program prices for individuals receiving prescription drugs through programs in departments described in Section 14572.

(3) Develop an outreach program to ensure that hospitals, clinics, and other eligible entities participate in the program authorized under Section 340B of the Public Health Service Act (42 U.S.C. Sec. 256b).

(b) The office, in consultation with the agencies listed in subdivision (a) of Section 14572, may investigate and implement other options and strategies to achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

14575. The office may appoint and contract with a pharmaceutical benefits manager or other entity for purposes of the prescription drugs purchased under this part. The pharmaceutical benefits manager or other entity may do all of the following:

(a) Negotiate price discounts, rebates, or other options that achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

(b) Purchase prescription drugs for participating state, district, county, or municipal governmental entities.

(c) Act as a consultant to the office.

14576. The office may explore additional strategies for managing the increasing costs of prescription drugs, including, but not limited to, all of the following:

(a) Coordinating programs offered by pharmaceutical manufacturers that provide prescription drugs for free or at reduced prices.

(b) Studying the feasibility and appropriateness of including in the bulk purchasing programs entities in the private sector, including employers, providers, and individual consumers.

(c) Implementing other strategies, as permitted under state and federal law, aimed at managing escalating prescription drug prices.

~~(d) It is the intent of the Legislature that the office, State Department of Health Services, University of California, and Public Employees' Retirement System share information on a regular basis on drug purchasing activities.~~

14577. On or before February 1, 2007, and annually thereafter, the office shall submit a report to the appropriate policy and fiscal committees of the Legislature on activities that have been or will be undertaken pursuant to this part. The report shall include, but not be limited to, all of the following:

(a) The number and a description of contracts entered into with manufacturers and suppliers of drugs pursuant to Section 14571, including any discounts, rebates, or refunds obtained.

(b) The number and a description of entities that elect to participate in the coordinated purchasing program pursuant to subdivision (b) of Section 14572.

(c) Other options and strategies that have been or will be implemented pursuant to Sections 14573 and 14575.

(d) Estimated costs and savings attributable to activities that have been or will be undertaken pursuant to this part.

~~(e) The identification of the collaborative activities that the office, State Department of Health Services, University of California, and Public Employees' Retirement System conducted in the past 12 months to reduce the cost of drug purchasing by the state and the savings attributable to those activities.~~

~~(f) The identification of opportunities to consolidate drug purchases with the University of California.~~

SEC. 3. Chapter 12 (commencing with Section 14977) of Part 5.5 of Division 3 of Title 1 of the Government Code is repealed.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 76 **VERSION: AMENDED MAY 2, 2005**

AUTHOR: FROMMER et. al. **SPONSOR: FROMMER**

RECOMMENDED POSITION: NO POSITION

SUBJECT: OFFICE OF PHARMACEUTICAL PURCHASING

Existing Law:

1) Authorizes the Department of General Services (DGS) to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. (Govt Code 14977-14981)

2) Requires four state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. (Govt Code 14977-14981)

This Bill:

1) Repeals these provisions authorizing DGS's drug purchasing program. (Govt Code 14977-14981 Repealed)

2) Creates the Office of Pharmaceutical Purchasing (Office) within California Health and Human Services Agency to purchase prescription drugs for the following entities:

a. California Department of Corrections (CDC)

b. Department of Mental Health (DMH)

c. California Youth Authority (CYA)

d. Department of Developmental Services (DDS)

e. Department of Veterans Affairs

f. California State University (CSU)

g. Any other state agency as directed by the Governor.

h. Any state, district, county, city, municipal, school district, joint powers agreement or trust that administers or pays public employee benefits, or public agency governmental entity that may elect to participate in the coordinated purchasing program. (Govt Code 12803 Amended, 14572 Added)

3) Requires the Office to work with the University of California (UC) to identify opportunities for consolidating the drug purchases made by both agencies in order to lower the state's costs for purchasing prescription drugs. (Govt Code 14573 Added)

4) Authorizes the office to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. The office may obtain from those manufacturers and suppliers, discounts, rebates, or refunds based on quantities purchased insofar, as permissible under federal law.

(Govt Code 14571 Added)

5) Authorizes the office to appoint and contract with a pharmaceutical benefits manager (PBM) or other entity to do all of the following:

a. Negotiate price discounts, rebates, or other options that achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

b. Purchase prescription drugs for participating state, district, county, or municipal governmental entities.

c. Act as a consultant to the office. (Govt Code 14575 Added)

6) Requires the office, on or before February 1, 2007, to submit a report to the Legislature on activities that have been or will be undertaken. The report would include the following:

a. The number and a description of contracts entered into with manufacturers and suppliers of drugs including any discounts, rebates, or refunds obtained.

b. The number and a description of entities that elect to participate in the coordinated purchasing program.

c. Other options and strategies that have been or will be implemented pursuant to receive the lowest cost drugs.

d. Estimated costs and savings attributable to activities that have been or will be undertaken by the office.

e. Identify the collaborative activities that the office, State Department of Health Services, University of California, and Public Employees' Retirement System conducted in the past 12 months to reduce the cost of drug purchasing by the state and the savings attributable to those activities.

(Govt Code 14577 Added)

Comment:

1) Author's Intent. The author's intent is to implement drug-purchasing recommendations made by the California Performance Review (CPR). CPR estimates that its drug purchasing proposals would result in $75 million in annual state savings.

2) Current DGS Drug Purchasing Program. DGS is responsible for procuring drugs for CDC DMH, DDS, CYA, and CSU's student health centers. DGS contracts with a vendor, McKesson Corporation, to process departmental drug orders and then distribute those orders to the departments. McKesson acquires the drugs through 1) competitively procured state contracts for generic drugs, 2) negotiated state contracts for brand-name drugs, or 3) the Massachusetts Alliance, a GPO consisting of both public and private agencies. For drugs that are not available through these methods, McKesson acquires the drugs at discounted wholesale prices.

3) LAO Report. A February 2005 Legislative Analyst Office (LAO) Report, Lowering the State's Costs for Prescription Drugs, examines how the state purchases drugs for its program recipients. The LAO report was critical of many elements in CPR's drug purchasing proposal, which are also found in AB 76. Specifically, the LAO found:

a. The use of a PBM would not benefit the state since the state already has established a drug formulary, authority to negotiate drug rebates, and usually does not purchase drugs from private pharmacies.

b. There is a limited need for a drug purchasing office given that the creation of a new office could be costly, create organizational difficulties, and provide little strategic advantage to the state over the current arrangement in which procurement duties are already largely concentrated.

Overall the LAO found the state's various drug-purchasing programs could take specific actions to improve on getting the lowest price possible for prescription drugs. Legislation would be required to implement most of the actions recommended by the LAO.

4) Support / Opposition.

Support: American Federation of State, County and Municipal Employees
California Alliance of Retired Americans
California Federation of Labor
California Public Interest Research Group
Consumers Union
Health Access
Mental Health Association of California
Older Women's League of California
Senior Action Network
Service Employees Union International

Opposition: Biocom
California Chamber of Commerce
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America
Western Center on Law & Poverty (unless amended)
Wyeth Pharmaceuticals

5) History.

June 22	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
June 20	In committee: Set, first hearing. Hearing canceled at the request of author.
June 15	Referred to Coms. on HEALTH and G.M., E. & A.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 42. Noes 34. Page 2141.)
May 27	Read second time. To third reading.
May 26	From committee: Do pass. (Ayes 12. Noes 5.) (May 25).
May 18	In committee: Set, first hearing. Referred to APPR. suspense file.
May 3	Re-referred to Com. on APPR.
May 2	Read second time and amended.
Apr. 28	From committee: Amend, and do pass as amended, and re-refer to Com. on APPR. (Ayes 7. Noes 1.) (April 26).
Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 9. Noes 3.) (April 12).
Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

AB 76

AMENDED: June 22, 2005

SENATE HEALTH
COMMITTEE ANALYSIS
Senator Deborah V. Ortiz, Chair

FISCAL: Government Modernization and Economic Development 6
/Appropriations

CONSULTANT:
Bohannon / ak

SUBJECT

Office of Pharmaceutical Purchasing

SUMMARY

This bill would repeal provisions of existing law authorizing the Department of General Services (DGS) to negotiate contracts for prescription drugs for specified state agencies and other entities. This bill would instead establish the Office of Pharmaceutical Purchasing (OPP) within the California Health and Human Services Agency (Agency) with authority and duties to purchase prescription drugs for state agencies similar to that granted to DGS. The bill would additionally require the OPP to be the purchasing agency for the California State University (CSU), any other state agency as directed by the Governor, and other entities that elected to participate in the purchasing program. The measure would also require the OPP to conduct specified activities in order to negotiate the lowest prices possible for prescription drugs.

ABSTRACT

Existing federal law:
1.Requires drug manufacturers, for the purposes of the federal Medicaid program, to enter into rebate agreements with the United States Secretary of Health and Human Services for states to receive federal funding for outpatient prescription drugs dispensed to Medicaid enrollees.

2.Permits a state, upon authorization from the Secretary, to enter directly into agreements with a drug

manufacturer to negotiate deeper discounts for state Medicaid programs.

3.Authorizes, for the purposes of the federal 340B program, the Secretary of Health and Human Services to enter into agreements with drug manufacturers to provide specified drugs to cover entities at discounted prices.

Existing state law:

1.Establishes the Medi-Cal program, California's Medicaid program, which provides health insurance coverage and prescription drug benefits for low-income families, children, and aged, blind, and disabled individuals.

2.Authorizes the Department of Health Services (DHS) to be the purchaser of prescribed drugs under the Medi-Cal program in order to obtain the most favorable prices from drug manufacturers. Authorizes DHS to obtain discounts, rebates, or refunds, as permissible by federal law.

3.Specifies that the Agency consists of the Office of Statewide Health Planning and Development and the State Council on Developmental Disabilities and includes the following departments:

- Health Services;
- Mental Health;
- Developmental Services;
- Social Services;
- Alcohol and Drug Abuse;
- Aging;
- Rehabilitation;
- Community Services and Development; and,
- Child Support Services.

1.Authorizes DGS to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with drug manufacturers and suppliers, and authorizes DGS to obtain discounts, rebates, or refunds as permissible under federal law.

2.Allows contracts entered into by DGS to include discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices. Exempts these contacts from specified provisions of the Public Contract Code.

3.Authorizes DGS to establish a bulk purchasing program and requires the following state entities to purchase drugs through the bulk purchasing program:

- State Department of Mental Health;
- Department of Corrections;

Department of the California Youth Authority; and,
State Department of Developmental Services.

1.Allows any state, district, county, city, municipal, or public agency governmental entity to elect to participate in the coordinated purchasing program.

2.Authorizes DGS, in consultation with the entities listed in #4, to investigate and implement other options and strategies to achieve the greatest savings on prescription drugs with drug manufacturers and wholesalers.

3.Authorizes DGS to appoint and contract with pharmaceutical benefits manager (PBM) or other entity to, among other things, negotiate price discounts, purchase prescription drugs, and act as a consultant to DGS.

4.Authorizes DGS to explore additional strategies for managing the increasing costs of prescription drugs including:

Coordinating programs offered by drug manufacturers that provide prescription drugs for free or at reduced prices;

Studying the feasibility and appropriateness of including in the bulk purchasing programs entities in the private sector, including employers, providers, and individual consumers; or,

Implementing other strategies, as permitted under state and federal law, aimed at managing escalating prescription drug prices.

This bill:

1.Establishes the OPP within the Agency to purchase prescription drugs for state agencies as specified.

2.Authorizes the OPP to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with drug manufacturers and suppliers, and authorizes the OPP to obtain discounts, rebates, or refunds as permissible under federal law.

3.Allows contracts entered into by the OPP to include discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices. Exempts these contacts from specified provisions of the Public Contract Code.

4.Requires the OPP to be the purchasing agency for prescription drugs for all of the following state

entities:
Department of Corrections;
State Department of Mental Health;
Department of the Youth Authority;
State Department of Developmental Services;
CSU; and
Any other state agency as directed by the Governor.

1.Allows any state, district, county, city, municipal, school district, joint powers agreement or trust that administers or pays public employee benefits, or public agency governmental entity to elect to participate in the coordinated purchasing program.

2.States legislative intent for the OPP, the University of California (UC), and the Public Employees' Retirement System (PERS) to regularly meet and share drug procurement information to identify and implement opportunities for cost savings.

3.Expresses the intent of the Legislature that UC and PERS cooperate with the OPP in order to reduce each agency's costs for prescription drugs.

4.Requires the OPP to do all of the following:
Share information on a regular basis with UC and PERS regarding each agency's procurement of prescription drugs;

Identify opportunities for the OPP, UC, and PERS to consolidate drug procurement or engage in other joint activities that will result in cost savings;

Participate in at least one independent association that develops information on the relative effectiveness of prescription drugs;

Develop a work plan that includes, but is not limited to, a description of the OPP's annual activities to reduce the state's costs for prescription drugs and an estimate of cost savings, no later than January 1, 2007, and annually thereafter; and,

Report to the chairperson of the Joint Legislative Budget Committee and the chairs of the fiscal committees of the Legislature on any joint activities of the OPP, UC, and PERS in the last 12 months in connection with procurement of prescription drugs and any resulting cost savings, including the work plan described above, no later than January 10, 2007, and

annually thereafter.

1. Specifies that nothing shall be construed to require sharing of information that is prohibited by any other provision of law or contractual agreement, or the disclosure of information that may adversely effect potential drug procurement by any state agency.

2. Authorizes the OPP to do all of the following in order to negotiate the lowest prices possible for prescription drugs:

   Establish a formulary or formularies for state programs in consultation with the affected agencies;

   Pursue all opportunities for the state to achieve savings through the federal 340B program including the development of cooperative agreements with entities covered under the 340B program that increase access to 340B program prices for specified individuals; and,

   Develop an outreach program to ensure that hospitals, clinics, and other eligible entities participate in the 340B program.

1. Authorizes the OPP, in consultation with the agencies listed in #4, to investigate and implement other options and strategies to achieve the greatest savings on prescription drugs with drug manufacturers and wholesalers.

2. Authorizes the OPP to appoint and contract with a PBM or other entity to, among other things, negotiate price discounts, purchase prescription drugs, and act as a consultant to the OPP.

3. Authorizes the OPP to explore additional strategies for managing the increasing costs of prescription drugs including, but not limited to,:

   Coordinating programs offered by drug manufacturers that provide prescription drugs for free or at reduced prices;

   Studying the feasibility and appropriateness of including in the bulk purchasing programs entities in the private sector, including employers, providers, and individual consumers; or,

   Implementing other strategies, as permitted under state and federal law, aimed at managing escalating

prescription drug prices.

1.Requires the OPP to submit a report to the appropriate policy and fiscal committees of the Legislature, on or before February 1, 2007, on activities that have been or will be undertaken.

2.Requires the report to include, but not be limited to, all of the following:

The number and description of contracts entered into with drug manufacturers and suppliers as specified, including any discounts, rebates, or refunds obtained;

The number and description of entities that elect to participate in the coordinated purchasing program as specified;

Other options and strategies that have been or will be implemented as specified; and,

Estimated costs and savings attributable to activities that have been or will be undertaken.

1.Repeals provisions of the Government Code authorizing DGS to negotiate contracts for prescription drugs for specified state agencies and other entities.

FISCAL IMPACT

According to the Assembly Appropriations Committee:

Assuming establishing an OPP results in increased staffing positions by three additional positions above the DGS staffing level, increased General Fund (GF) cost of $306,000. This assumes that the two staff positions and $224,000 in spending in DGS are transferred to the OPP.

Assuming the OPP meets the requirement that it participate in at least one independent group that develops information on the relative effectiveness of prescription drugs by participating in the Oregon Effectiveness Review Project, a total funds cost of approximately $100,000 annually.

Unknown, potentially significant increased out-year revenue from increased state purchasing power in negotiating with drug manufacturers. Based on 2003 - 04 expenditures, if drug expenditures for the Departments of Corrections, Mental Health, Youth Authority, Developmental Services, and the California State

University were reduced by 10 percent annually, total fund savings of $17.7 million would result.

BACKGROUND AND DISCUSSION

Purpose of bill

According to the author, AB 76 will enable the state to take better advantage of its bargaining power to hold down the cost of prescription drugs. The author maintains that both the Legislative Analyst's Office (LAO) and the California Performance Review (CPR) found major deficiencies in the way the state is currently purchasing prescription drugs and recommend a number of changes, many of which are incorporated in this bill. The author believes the state can save millions of dollars in programs that purchase prescription drugs and redirect those savings to maintain health, education, transportation, and other programs that are threatened by the state's current budget deficit.

State drug purchasing and costs

According to the Congressional Budget Office, the growth in prescription drug costs has outpaced every other category of health expenditure. California, like all other states, has experienced this growth in prescription drug costs. According to a 2002 Bureau of State Audits review, the five state agencies that most frequently purchase drugs experienced an annual average increase of 34 percent in their drug costs from 1996 to 2001. The overall cost of drug expenditures for these five agencies rose from $41.6 million in 1996-97 to $153.6 million in 2002-03. According to the LAO, state agencies purchase approximately $4.2 billion annually in prescription and nonprescription drugs. These agencies use different methods to purchase discounted drugs which include contracting directly with drug manufacturers and wholesalers, utilizing Group Purchasing Organizations or PBMs, or negotiating directly with health care benefit plans.

The CPR

The CPR, initiated by the Governor, called for the state to take immediate steps to purchase drugs in a more coordinated, unified fashion. The CPR noted that several state agencies purchase drugs independently of each other, weakening the state's ability to bargain aggressively for better prices. The CPR said that:

> "Although the state's purchasing power should equate to a strong market position and lower drug prices, this is not the case. Several of the state agencies purchasing drugs do so independently of each other and

thus segment themselves into smaller markets. Although each state entity may do an admirable job of negotiating drug prices, this practice weakens their market position and results in higher drug costs. Working together to combine drug purchases would significantly increase their volume purchasing power thus establishing a stronger market position leading to lower drug costs."

The CPR recommended that the Governor and Legislature should work together to create a new Central Pharmaceutical Office that should be responsible for the procurement and management of all pharmaceutical programs. The CPR also recommended that this office should have the authority to establish cooperative relationships with local governments, other state entities and drug manufacturers in order to maximize the state's purchasing power. Finally, the CPR recommended that DGS, or its successor, enter into a contract with a PBM to administer the state's drug purchasing program.

Additionally, the CPR showed that safety net providers are able to obtain prescription drugs for their patients at a 50 percent discount off of retail prices through the federal 340B program. The federal 340B program permits various "covered entities," mostly safety net health care providers like community clinics and disproportionate-share public and private hospitals, to obtain steeply-discounted drugs for patients of those providers. Utilizing 340B prices for state programs could save the state millions of dollars through the use of cooperative agreements between the state and safety net providers that would allow the state to access these prices.

The LAO report
A recent LAO report, Lowering the State's Costs for Prescription Drugs, identified a range of deficiencies in the state's procurement of prescription drugs which lead to higher costs than necessary. For example, the report found that DGS is not providing sufficient leadership in drug procurement. Specifically, the report found that DGS has no comprehensive work plan or strategy for aggressively lowing drug costs; DGS purchases almost half of its drugs without contracts, which results in the state paying higher prices; and DGS does not participate in independents groups that review the comparative effectiveness of similar drugs. The report also found that there is insufficient collaboration among state agencies in their drug purchasing.

Among other things, the LAO recommended the Legislature

should:

Require collaboration and information sharing on drug purchasing among DGS, the DHS, UC and PERS;

Direct DGS and UC to identify consolidated purchasing opportunities;

Require DGS to develop an annual work plan for purchasing drugs;

Require DGS participation in evidence-based drug reviews by outside entities; and,

Direct DHS to modify formulary regulations to permit the Department of Mental Health and the Department of Developmental Services to have one formulary committee to serve all of an agency's facilities, rather than require each facility to have a formulary.

AB 76 essentially transfers the drug purchasing and coordination authority in existing law from DGS to the newly created OPP and builds upon that authority based upon the aforementioned recommendations by the CPR and LAO.

Drug purchasing coordination efforts in other states
In 2003, the Governor of Illinois created a Special Advocate for Prescription Drugs to provide strategic coordination of prescription drug contracts and programs by a central state purchasing agent. In late 2004, the Governor of West Virginia created a cabinet level Pharmaceutical Special Advocate to direct state government procurement of prescription drugs. The state of Maine, in its recently enacted 2005-06 budget, established a Pharmaceutical Cost Management Council to jointly purchase drugs for a number of state programs. Currently, Massachusetts and Pennsylvania also have centralized purchasing initiatives underway.

Arguments in support
Supporters of the bill believe AB 76 would significantly increase the state's purchasing clout and enable California to garner lower prescription drug prices. They insist that the state's current drug procurement process is fragmented resulting in higher costs than necessary to California taxpayers. They believe that while recent legislation has sought to improve coordination, progress toward real collaboration among state drug purchasers has been slow and limited. They also believe the purchasing power amassed under AB 74 will result in significant savings to the state budget. Further, supporters maintain that the new Medicare

prescription drug law will reduce the effectiveness of Medi-Cal prescription drug purchasing efforts while requiring the state to pay the federal government. Supporters insist that by helping to reduce prescription drug costs for other state programs, AB 76 helps to remedy the damage done by the new Medicare prescription drug law.

Arguments in opposition
Opponents of the bill believe AB 76 is premature and unnecessary since DGS was just granted authority to negotiate discounts with drug companies in 2002. They argue that abolishing a program created only two years ago, in order to create a new bureaucracy for the same purpose is not only premature, but is also an inappropriate waste of state resources. Further, they insist that proposed aggregate purchasing programs for multiple patient populations may not meet the medical needs of individual patients given that diverse patient populations have unique clinical needs that must be met in their own distinctive manner. As such, they insist the state may find it more complicated than anticipated to combine purchasing for each population without compromising the quality of care and the integrity of the program benefits. Lastly, opponents believe AB 76 contains provisions that allow for closed formularies. They believe that limited formularies are counter to the mission of biotechnology which is based on the premise that even within classes of drugs, there are significant differences in products. As such, they insist that limiting the number of drugs within a formulary essentially limits therapeutic options for patients.

Relevant legislation
SB 708 (Speier, 2005) would require DHS to develop a standard contract for use in any agreement with a not-for-profit hospital that elects to participate in the federal 340B program.

SB 1315 (Sher, Chapter 483, Statutes of 2002) requires DGS to purchase pharmaceuticals on behalf of the Department of Corrections, Department of Mental Health, Department of Youth Authority, and Department of Developmental Services. Allows any other state, county, city, municipal or public agency government entity, to elect to participate in the coordinated purchasing program.

QUESTIONS AND COMMENTS

1.PBM protections. AB 76 authorizes the OPP to appoint and contract with a PBM or other entity to provide consulting

and pharmacy benefit management services. Last week the committee passed AB 78 (Pavley) which seeks to provide transparency in PBM contracting by requiring a PBM to annually disclose specified confidential proprietary information to a purchaser. AB 78 is premised on the notion that some PBMs engage in questionable business practices resulting in higher prescription drug costs for the purchaser. As such, should AB 76 be amended to require the OPP to develop a system to prevent diversion of funds collected by the PBM or other entity it may appoint and contract with to provide consulting and pharmacy benefit management services?

2. Is AB 76 duplicative of SB 1315? AB 76 essentially transfers the drug purchasing and coordination authority in existing law created pursuant to SB 1315 (Sher, Chapter 483, Statutes of 2002) from DGS to the newly created OPP and builds upon that authority based upon recommendations by the CPR and LAO. LAO recommendations, however, focused on bolstering DGS' capacity, leadership and coordination in drug purchasing, but nonetheless, left that authority within the department. Given the same statutory authority and additional requirements, does the author believe DGS could accomplish the same goals as the OPP?

PRIOR ACTIONS

Assembly Floor: 42 - 34 Pass
Assembly Appropriations: 12 - 5 Do Pass
Assembly Bus. & Prof: 7 - 1 Do Pass as Amended
Assembly Health: 9 - 3 Do Pass

POSITIONS

Support: AFSCME
California Alliance for Retired Americans
California Consumers United
California Labor Federation
California School Employees Association
CALPIRG
Consumers Union
Gray Panthers
Health Access
Health Care for All - California
Mental Health Association in California
Older Women's League of California
Planned Parenthood Affiliates of California
Retired Public Employees Association
SEIU

Oppose: BIOCOM
California Chamber of Commerce
Novartis
PhRMA

AMENDED IN SENATE JUNE 23, 2005

AMENDED IN ASSEMBLY APRIL 18, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 78

Introduced by Assembly Member Pavley
(Coauthors: Assembly Members Bass, Chan, Evans, Frommer, Gordon, and Koretz)

January 3, 2005

An act to add Division 113 (commencing with Section 150000) to the Health and Safety Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 78, as amended, Pavley. Pharmacy benefits management.

Existing law provides for the regulation of health care benefits.

This bill would define the term "pharmacy benefits management" as the administration or management of prescription drug benefits. The bill would also define the term "pharmacy benefits manager" as an entity that performs pharmacy benefits management. The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers, including specified information about the pharmacy benefit manager's revenues. The bill would also establish certain standards and requirements with regard to pharmacy benefits management contracts.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 113 (commencing with Section 150000) is added to the Health and Safety Code, to read:

DIVISION 113. PHARMACY BENEFITS MANAGEMENT

150000. For purposes of this division, the following definitions shall apply:

(a) "Labeler" means any person who receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration under Section 207.20 of Title 21 of the Code of Federal Regulations.

(b) "Pharmacy benefits management" is the administration or management of prescription drug benefits. Pharmacy benefits management shall include all of the following: the procurement of prescription drugs at a negotiated rate for dispensation within this state, the processing of prescription drug claims, and the administration of payments related to prescription drug claims.

(c) "Pharmacy benefits manager" is any entity that performs pharmacy benefits management. The term does not include a health care service plan or health insurer if the health care service plan or health insurer offers or provides pharmacy benefits management services and if those services are offered or provided only to enrollees, subscribers, or insureds who are also covered by health benefits offered or provided by that health care service plan or health insurer, nor does the term include an affiliate, subsidiary, or other related entity of the health care service plan or health insurer that would otherwise qualify as a pharmacy benefits manager, as long as the services offered or provided by the related entity are offered or provided only to enrollees, subscribers, or insureds who are also covered by the health benefits offered or provided by that health care service plan or health insurer.

(d) "Purchaser" is any entity that enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefit management services.

150001. (a) The contract entered into between the pharmacy benefits manager and the purchaser shall include both of the following:

(1) A disclosure in writing of any fees to be charged for drug utilization reports requested by the purchaser.

(2) The terms of confidentiality for any information received by the purchaser pursuant to subdivision (b).

(b) Except as provided in Section 150002, a pharmacy benefits manager shall provide all of the following information no less frequently than once each year and, at the request of the purchaser, within 30 days of receipt of the request by the purchaser:

(1) The aggregate amount, for a list of drugs to be specified in the contract, of all rebates and other retrospective utilization discounts that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with the purchasing or dispensing of prescription drugs for individuals receiving *services* under the purchaser's contract.

(2) The nature, type, and amount of all revenue the pharmacy benefits manager receives, directly or indirectly, from each pharmaceutical manufacturer or labeler for any other products or services provided by the pharmacy benefits manager with respect to programs that the purchaser contracts with the pharmaceutical benefits manager to provide.

(3) Any prescription drug utilization information requested by the purchaser relating to utilization by the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser.

(4) Any financial arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

(5) Any financial arrangements related to the provision of pharmacy benefits management for the purchaser that exist between the pharmacy benefits manager and any brokers, consultants, consulting companies, or other intermediaries.

150002. (a) A pharmacy benefits manager is not required to make the disclosures required in Section 150001 unless and until

the purchaser agrees in writing to maintain the disclosed information as confidential proprietary information. The agreement may provide for equitable and legal remedies in the event of a violation of this confidentiality provision. The agreement may authorize the purchaser to disclose the confidential proprietary information to persons or entities with whom the purchaser contracts to provide consultation regarding pharmacy services and may require those persons or entities to treat the information as confidential proprietary information.

(b) For purposes of this section, "proprietary information" includes trade secrets and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers, and personnel held by a pharmacy benefits manager and used for its business purposes.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 78 **VERSION: AMENDED June 23, 2005**

AUTHOR: PAVLEY **SPONSOR: PAVLEY**

RECOMMENDED POSITION: NO POSITION

SUBJECT: PHARMACY BENEFIT MANAGEMENT

Existing Law:

Provides for the regulation of HMOs and the benefits they provide by the Department of Managed Health Care.

This Bill:

1) Defines "labeler" as any person who repackages prescription drugs for later sale and who has a labeler code issued by the Food and Drug Administration (FDA). (H&S 150000 Added)

2) Defines "pharmacy benefits management" as the administration or management of prescription drug benefits including:

a. The procurement of prescription drugs at a negotiated rate for dispensing,

b. The processing of prescription drug claims,

c. The administration of payments related to prescription drug claims.

(H&S 150000 Added)

3) Defines "pharmacy benefits manager" (PBM) as an entity that performs "pharmacy benefits management" as defined. (H&S 150000 Added)

4) Exempts health care service plans or health insurers if they perform pharmacy benefits management directly, or through a subsidiary, exclusively for their enrollees or insureds. (H&S 150000 Added)

5) Defines "purchaser" as any entity that enters into an agreement with a PBM for the provisions of pharmacy benefit management services. (H&S 150000 Added)

6) Defines "proprietary information" to include trade secretes and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers, and personnel held by a pharmacy PBM and used for its business purposes. (H&S 150002 Added)

7) Requires contracts entered into between a PBM and a purchaser to include:

a. A disclosure in writing of any fees to be charged fro drug utilization reports requested by the purchaser; and

b. The terms of confidentiality for any information received by the purchaser.

(H&S 150001 Added)

8) Requires a PBM to disclose to the purchaser the following, no less than once a year, and at the request of the purchaser, within 30 days of the request:

a. The aggregate amount of all rebates that the pharmacy benefits manager receives from pharmaceutical manufacturers in connection with prescription drug benefits related to the purchaser.

b. The nature, type, and amount of all other revenue that the pharmacy benefits manager receives from pharmaceutical manufacturers in connection with prescription drug benefits related to the purchaser.

c. Any prescription drug utilization information related to the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser.

d. Any arrangements with prescribers, medical groups, individual practice associations, or pharmacists that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

e. Any financial arrangements related to the provision of pharmacy benefits management to the purchaser that exist between the pharmacy benefits manager and any brokers, consultants, consulting companies, or other intermediaries.

(H&S 150001 Added)

9) Allows a PBM not to disclose required information in H&S 150001 unless a purchaser agrees in writing to maintain the disclosed information confidential and proprietary information. The agreement may provide for equitable and legal remedies in the event of a violation of the confidentiality provision. (H&S 150002 Added)

Comment:

1) Author's Intent. According to the author, this bill is needed to create consumer protection guidelines that PBMs must meet when doing business with California clients such as CalPERS, large employers, health plans, and union trust funds. The author believes that creating a more transparent market will shine a light on an industry that discloses an inadequate amount of pricing and conflict of interest information and will enable clients to make informed decisions about the type of prescriptions and benefits they select on behalf of their enrollees. According to the author, this will allow clients to take full advantage of the free market by incentivizing PBMs to compete in a fair, transparent environment for California business.

2) PBM Task Force. The board convened a task force on PBM regulation in 2003. The task force conducted a thorough evaluation of PBM practices to determine whether establishing state regulation of PBMs was necessary. The task force was unable to identify a clear need for regulation of PBMs. The task force was unable to define an existing or potential consumer harm that could be remedied by the regulation of PBMs. The areas of greatest potential concern, as expressed by participants, were related to the business and contractual relationships between PBMs and their clients (health plans, employers, trust funds, etc.) that would be best resolved by those parties in their negotiations.

3) State Legislation. AB 1960 (Pavley 2004), Pharmacy Benefit Management, was introduced last session and passed through the Legislature. Governor vetoed the bill. In his veto message the Governor stated "this measure would have the unintended consequence of increasing drug costs to health plans, the Medi-Cal Program and other purchasers, without providing any real consumer benefit. Studies, including one from the Federal Trade Commission, have shown that enactment of this legislation will limit competition and significantly increase the cost of prescription drugs."

4) Other States: Maine was the first state to pass a PBM disclosure law. Shortly after passage, the law was challenged in the courts by the Pharmaceutical Care Management

Association. The lawsuit claimed that Maine's Unfair Prescription Drug Practices Act is preempted by federal law, would effect a regulatory taking of trade secrets and revenues, and violates due process, freedom of speech and the Commerce Clause of the Constitution.

States that rejected PBM disclosure laws in 2004 include California, Florida, Iowa, Kansas Maryland, Minnesota, Mississippi, New York, Vermont and Washington, the association said.

5) Support / Opposition.

Support: AFSCME
AIDS Healthcare Foundation
California Alliance for Retired Americans
California Labor Federation
California Pharmacists Association
California School Employees Association
California Nurses Association
CalPERS Board of Administration
CALPIRG
Consumers Union
Gray Panthers
Greenlining Institute
Health Access
Older Women's League of California
Retired Public Employees Association
SEIU

Opposition: America's Health Insurance Plans
California Chamber of Commerce
Express Scripts, Inc
Health Net
Medco Health Solutions

6) History.

2005

June 23	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on JUD.
June 23	From committee: Do pass, and re-refer to Com. on JUD. Re-referred. (Ayes 6. Noes 3.).
June 9	Referred to Coms. on HEALTH and JUD.
June 2	In Senate. Read first time. To Com. on RLS. for assignment.
June 1	Read third time, passed, and to Senate. (Ayes 44. Noes 34. Page 2051.)
Apr. 28	Read second time. To third reading.
Apr. 27	From committee: Do pass. (Ayes 6. Noes 3.) (April 26).
Apr. 19	Re-referred to Com. on B. & P.
Apr. 18	Read second time and amended.
Apr. 14	From committee: Amend, do pass as amended, and re-refer to Com. On B. & P. (Ayes 10. Noes 4.) (April 12).
Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print. (Corrected January 10.)

AB 78

AMENDED: April 18, 2005

SENATE HEALTH
COMMITTEE ANALYSIS
Senator Deborah V. Ortiz, Chair

FISCAL: Judiciary/ NonFiscal
8

CONSULTANT:
Bohannon / ak

SUBJECT

Pharmacy benefits management

SUMMARY

This bill would require a contract between a pharmacy benefits manager (PBM) and a purchaser, as defined, to disclose any fees to be charged for drug utilization reports requested by the purchaser and to additionally specify the terms of confidentiality for specified proprietary information received by the purchaser upon annual disclosure by the PBM or at the request of the purchaser.

ABSTRACT

Existing law:
1. Provides for the regulation of health plans by the Department of Managed Health Care (DMHC) and for the regulation of health insurers by the California Department of Insurance (CDI.

2. Requires every plan that covers prescription drug benefits to provide notice in the evidence of coverage and disclosure form to enrollees regarding whether the plan uses a formulary.

3. Requires the notice to include an explanation of what a formulary is, how the plan determines which prescription drugs are included or excluded, and how often the plan reviews the content of the formulary.

4. Requires every plan that covers prescription drug benefits to provide to members of the public, upon request, information regarding whether a specific drug or drugs are on the plan's formulary. Requires notice of the opportunity to secure this information from the plan to be included in the evidence of coverage and disclosure form to enrollees.

5.Requires every plan to notify enrollees, and members of the public who request formulary information, that the presence of a drug on the formulary does not guarantee that an enrollee will be prescribed that drug by his or her prescribing provider for a particular medical condition.

6.Requires health plans that provide prescription drug benefits to maintain an expeditious process by which prescribing providers can obtain authorization for a medically necessary nonformulary prescription drug.

This bill:

1.Defines "labeler" to mean any person who receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration.

2.Defines "pharmacy benefits management" to mean the administration or management of prescription drug benefits including all of the following:

The procurement of prescription drugs at a negotiated rate for dispensation within this state;

The processing of prescription drug claims; and,

The administration of payments related to prescription drug claims.

1.Defines "PBM" to mean any entity that performs pharmacy benefits management excluding:

A health care service plan or health insurer if the plan or insurer offers or provides pharmacy benefits management services and if those services are offered or provided only to enrollees, subscribers, or insureds who are also covered by health benefits offered or provided by that plan or insurer; or,

An affiliate, subsidiary, or other related entity of the health care service plan or health insurer that would otherwise qualify as a PBM, as long as services offered or provided by the related entity are offered or provided only to enrollees, subscribers, on insureds who are also covered by the health benefits offered or provided by that health service plan or health insurer.

1.Defines "purchaser" to mean any entity that enters into an agreement with a PBM for the provision of pharmacy benefit management services.

2.Requires the contract entered into between the PBM and the purchaser to include both of the following:

A disclosure in writing of any fees to be charged for drug utilization reports requested by the purchaser; and,

The terms of confidentiality for any information received by the purchaser from the PBM.

1.Requires a PBM to provide all of the following information no less frequently than once each year and, at the request of the purchaser, within 30 days of receipt of the request by the purchaser:

The aggregate amount, for a list of drugs to be specified in the contract, of all rebates and other retrospective utilization discounts that the PBM receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with the purchasing or dispensing of prescription drugs for individuals receiving _____ under the purchaser's contract;

The nature, type, and amount of all revenue the PBM receives, directly or indirectly, from each pharmaceutical manufacturer or labeler for any other products or services provided by the PBM with respect to programs that the purchaser contracts with the PBM to provide;

Any prescription drug utilization information requested by the purchaser relating to utilization by the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser;

Any financial arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with the activities of the PBM to encourage formulary compliance or otherwise manage prescription drug benefits; and,

Any financial arrangements related to the provision of pharmacy benefits management for the purchaser that exist between the PBM and any brokers, consultants, consulting companies, or other intermediaries.

1.Provides that a PBM is not required to make the specified disclosures noted above unless and until the purchaser agrees in writing to maintain the disclosed information as confidential proprietary information.

2.Allows the agreement to provide for equitable and legal remedies in the event of a violation of the confidentiality provision.

3.Allows the agreement to authorize the purchaser to disclose the confidential proprietary information to persons or entities with whom the purchaser contracts to provide consultation regarding pharmacy services and may require those persons or entities to treat the information as confidential proprietary information.

4.Includes as "proprietary information" trade secrets and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers, and personnel held by a PBM and used for its business purposes.

FISCAL IMPACT

BACKGROUND AND DISCUSSION

Purpose of bill
According to the author, AB 78 is needed to provide transparency in PBM contracting and will allow consumers to receive the full benefits of the rebates PBMs receive from pharmaceutical manufacturers. The author notes that the California Public Employees Retirement System (CalPERS) and other large employers in the state use PBMs to manage their prescription drug benefits. According to the author, since the late 1990's, PBMs have been investigated and sued by state governments, consumer and labor groups, the Federal Trade Commission, and U.S. Department of Justice. These investigations have targeted the refusal of PBMs to disclose the payments they receive from drug manufacturers and the practice of "drug switching" whereby PBMs steer customers toward more expensive drugs promoted by manufacturers. The author states that Maine and South Dakota have already enacted similar legislation and that numerous objective studies have highlighted the need for increased transparency within the PBM industry.

PBMs
PBMs are independent specialty administrators focusing on administering pharmacy benefits and managing the purchasing, dispensing, and reimbursing of prescription drugs. According to the California Healthcare Foundation, about 45% of the U.S. population has pharmacy coverage provided directly by a PBM. PBMs offer health plans a variety of services including negotiating price discounts with retail pharmacies, negotiating rebates with drug manufacturers, and operating mail-order prescription services and administrative claims processing systems. PBMs also provide health plans with clinical services such as formulary development and management, prior authorization, and drug utilization reviews to screen prescriptions for such issues as adverse interactions or therapy duplication. In order to provide these services, PBMs operate with multiple stakeholders in a complex set of relationship involving health plans, enrollees, pharmacies, and pharmaceutical manufacturers.

Major criticisms of PBMs
Conflicts of interest. Some PBMs are owned by drug manufacturers, pharmacy chains or insurance plans, and may additionally have undisclosed contracts with manufacturers to market or test their products.

Side deals and/or undisclosed payments and failure to pass savings along to consumers. Some PBMs negotiate additional discounts or rebates from drug manufacturers or pharmacies which they fail to pass on to consumers.

"Drug switching" to maximize rebate payments. Some PBMs have developed formularies that steer clients to higher-priced drugs and receive financial compensation for doing so. Additionally, some PBMs have been accused of substituting patient medication, without patient notification or authorization, for financial incentives.

Refusal to be audited or release information on pricing structure, rebate deals and other fee structures. PBM negotiations are based on the internal disclosure of confidential proprietary information among manufacturers, pharmacies, and health plans, much of which can not be publicly disclosed. However, the PBM industry has long been criticized for not being forthcoming regarding the additional compensation or incentives they receive that may unduly influence their business decisions.

General Accounting Office (GAO) report on PBMs
In January 2003, the GAO released a report entitled, "Federal Employees' Health Benefits: Effects of Using PBMs on Health Plans, Enrollees, and Pharmacies." The GAO's findings were generally positive stating that the PBMs reviewed produced savings for health plans by obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through mail-order pharmacies, passing on certain manufacturer rebates to the plans, and operating drug utilization control programs. The GAO found that the average price PBMs obtained from retail pharmacies for 14 brand name drugs was about 18 percent below the average price paid by customers without third-party coverage.

Additionally, the report found that plan enrollees had wide access to retail pharmacies, coverage of most drugs, and benefited from cost savings generated by the PBMs. However, pharmacy associations reported that PBMs large market share leaves little leverage in negotiating with PBMs. The plans and PBMs reviewed provided technical comments and two independent reviewers stated the report was fair and balanced. In written response to the report, one pharmacy association expressed strong concerns that the report did not more broadly address economic relationships in the PBM industry. However, the GAO stated that relationships between PBMs and other entities for other plans were beyond the scope of the report.

Brief timeline of PBM related litigation
2005
In May 2005, the U.S. Department of Education joined Arkansas, Florida, Tennessee, and Texas in a

whistleblower lawsuit alleging PBM Caremark avoided its obligation to reimburse Medicaid and other federal health insurance programs.

In April 2005, a U.S. District Court upheld Main's PBM legislation which was passed in 2003. The court stated: "This lack of transparency also has a tendency to undermine a benefits provider's ability to determine which is the best proposal among competing proposals from PBMs. In other words, although PBMs afford a valuable bundle of services to benefits providers, they also introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription drug costs."

2004

On August 4, 2004, New York Attorney General Elliot Spitzer sued Express Scripts, Inc. alleging the company pocketed as much as $100 million in drug rebates that should have gone to the state. The contract required the company to negotiate the lowest prices and return any rebates to the state, however Spitzer contents that Express Scripts called the rebates an administrative fee or similar term and kept them.

On April 26, 2004, Medco paid $29 million to settle a federal lawsuit brought by 20 state Attorneys General, including California's Attorney General Bill Lockyer. The case involved the practice of "switching," in which PBMs receive a fee for substituting one medication for another, without a patient's knowledge or consent. The PBM switches were not made for medical reasons and instead resulted from deals that drug companies have with PBMs.

2003

In 2003, Medco paid $42 million to settle a class-action lawsuit alleging that the company improperly promoted higher priced drugs promoted by its parent pharmaceutical company, rather than seeking the best price from alternative pharmaceutical companies.

In March 2003, the Prescription Access Litigation Project, in collaboration with the American Federation of State, County and Municipal Employees, brought suit against Medico, Caremark, Express Scripts, and Advance PCS, using California's unfair competition law, charging that they negotiated rebates from drug manufacturers and discounts from retail pharmacies, yet have not passed those savings onto healthcare plans and consumers.

Arguments in support

Supporters of the bill believe current law does nothing to ensure that a PBM is motivated to get the best drug prices for its clients. As such, they believe PBMs are serving the interests of drug manufacturers and themselves at the expense of their clients, including the state of California. Supporters believe AB 78 would provide PBM clients with accurate information about the discounts and incentives the PBM receives in connection with a given client's business. They insist that PBMs regularly receive rebates, discounts, and other financial incentives from drug manufacturers for steering consumers toward particular drugs. They argue that PBMs do not pass these "kickbacks" on to consumers and further, do not disclose to their clients that such deals exist. They insist that within such a dynamic, PBMs have an incentive to steer consumers toward those drugs that create the largest "spread," which are often the highest-priced drugs on the market. Additionally, supporters of the bill have grave concerns regarding how much the PBM industry is contributing to the high costs of prescription drugs and believe AB 78 would require better standards on a largely unregulated and growing industry.

Arguments in opposition
Opponents of bill insist that AB 78 unnecessarily and inappropriately intrudes on private-sector transactions between sophisticated entities that have access to expert consultants to assist them in negotiating the best deal to meet their needs. They believe AB 78 will ultimately increase prescription drug costs for California employers and consumers by severely compromising the ability of PBMs to negotiate discounts with drug manufacturers. Additionally, opponents of the bill object to what they view as a "one-size-fits-all" approach with respect to private PBM contracts. They insist that such requirements should not be dictated by the state, but should be negotiated between parties in general, but even more so when the parties are sophisticated, as is the case in PBM negotiations. They additionally assert that imposing specific contract requirements in law for the PBM industry and the large providers and employers with whom they contract would set a bad precedent for other industries. While they acknowledge that the bill recognizes and provides a legal remedy in the event that proprietary information is inappropriately disclosed, they maintain that in such an event, the damage would have already been done.

Prior legislation
AB 1960 (Pavley, 2004) would have required PBMs to disclose to purchasers or prospective purchasers information pertaining to rebates, discounts and other financial information and additionally would have required certain provisions to be included in contracts between a PBM and a purchaser. AB 1960 also would have established conflict of interest standards for members of

the PBM pharmacy and therapeutics committee and would have required PBMs to meet certain conditions prior to switching a patient from one drug to another. This measure was vetoed by the Governor on the grounds that the bill would have the unintended consequence of increasing drug costs to health plans, the Medi-Cal program and other purchasers, without providing any real consumer benefit.

Clarifying amendment
Clarifying/ technical amendment the author may wish to consider:

On page 3, line 18, after "receiving" insert "services"

PRIOR ACTIONS

Assembly Floor: 44 - 34 Pass
Assembly Bus. & Prof.: 6 - 3 Do Pass
Assembly Health: 10 - 4 Do Pass

POSITIONS

Support: AFSCME
AIDS Healthcare Foundation
California Alliance for Retired Americans
California Labor Federation
California Pharmacists Association
California School Employees Association
California Nurses Association
CalPERS Board of Administration
CALPIRG
Consumers Union
Gray Panthers
Greenlining Institute
Health Access
Older Women's League of California
Retired Public Employees Association
SEIU

Oppose: America's Health Insurance Plans
California Chamber of Commerce
Express Scripts, Inc
Health Net
Medco Health Solutions

AMENDED IN ASSEMBLY JUNE 21, 2005

AMENDED IN SENATE MAY 10, 2005

AMENDED IN SENATE MARCH 29, 2005

SENATE BILL No. 798

Introduced by Senator Simitian

February 22, 2005

An act to add Division 115 (commencing with Section 150000) to the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 798, as amended, Simitian. Prescription drugs: collection and distribution program.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to dispense a medication on prescription in a container that meets the requirements of state and federal law and is correctly labeled.

This bill would authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. The bill would require a county that elects to establish a repository and distribution program to establish procedures for, at a minimum, (1) establishing eligibility for medically indigent patients who may participate in the program, (2) ensuring that eligible patients are not charged for any medications provided under the program, (3) ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacist, and (4) ensuring the privacy of individuals for whom the medication was originally

prescribed. The bill would authorize any drug manufacturer legally authorized under federal law to manufacture or sell pharmaceutical drugs, *or a* licensed health facility, *pharmacy wholesaler,* or pharmacy to donate medications pursuant to these provisions. *Except in cases of bad faith or gross negligence, the bill would prohibit certain people and entities from being subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the bill's provisions.*

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 115 (commencing with Section 150000) is added to the Health and Safety Code, to read:

DIVISION 115. SURPLUS MEDICATION COLLECTION AND DISTRIBUTION

150000. It is the intent of the Legislature in enacting this division to authorize the establishment of a voluntary drug repository and distribution program for the purpose of distributing surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

150002. A health facility licensed under Chapter 2 (commencing with Section 1250) of Division 2, *a pharmacy wholesaler licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code,* a pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, and a drug manufacturer that is legally authorized under federal law to manufacture and sell pharmaceutical drugs, may donate excess or surplus unused prescribed medications under a program established by a county pursuant to this division.

150004. (a) A county may establish, by local ordinance, a repository and distribution program for purposes of this division.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacist by ensuring, at a minimum, all of the following:

(A) That only those drugs that are received and maintained in their unopened, tamper-evident packaging are dispensed.

(B) That any drugs received have not been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia or the product manufacturer.

(C) That any drugs received are dispensed prior to their expiration date.

(D) That reasonable methods have been established to ensure that drugs received have not been in the possession of any individual member of the public.

(E) That a pharmacist may use his or her discretion and best judgment in deciding whether or not to accept any donated drug.

(F) That records are kept for at least three years from the date that any drug is received or dispensed, whichever is later, pursuant to this division.

(G) That pharmacists adhere to standard pharmacy practices as required by state and federal law when dispensing all prescription drugs, including narcotics and other controlled substances.

(H) That donated drug stock is stored separately from a pharmacy's general supply for inventory, accounting, and inspection purposes.

(I) That any county that elects to dispense narcotics and other controlled substances is required to receive public comment from local law enforcement prior to establishing local protocols for packaging, transporting, storing, and distributing narcotics and other controlled substances.

(J) That local protocols established pursuant to this act adhere to any applicable requirements established by the California State Board of Pharmacy regarding packaging, transporting, storing,

and dispensing all prescription drugs, including narcotics and controlled substances.

(K) That county protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health and Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at their appropriate temperatures and according to any applicable standards established by the California State Board of Pharmacy.

(L) That, notwithstanding any other provision of law, participating pharmacies adhere to the same procedural drug pedigree requirements for donated drugs as they would for drugs purchased from a wholesaler or directly from a drug manufacturer.

(4) Ensuring the privacy of individuals for whom the medication was originally prescribed.

150005. The following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:

(a) A prescription drug manufacturer, pharmacy wholesaler, governmental entity, or health facility.

(b) A pharmacist or health care professional who accepts or dispenses prescription drugs.

(c) A pharmacy or health facility that employs a health care professional who accepts or can legally dispense prescription drugs.

150006. The immunities provided in Section 150005 shall not apply in cases of bad faith or gross negligence.

150007. Nothing in this division shall affect disciplinary actions taken by licensing and regulatory agencies.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 798 **VERSION: AMENDED MAY 10, 2005**

AUTHOR: SIMITIAN **SPONSOR: SIMITIAN**

RECOMMENDED POSITION: NO POSITION

SUBJECT: HEALTH CARE SERVICE PLANS: PREEXISTING CONDITIONS
PRESCRIPTION DRUGS: COLLECTION

Existing Law:

Pharmacy Law provides for the licensure and regulation of pharmacists by the board and authorizes a pharmacist to dispense a medication on prescription in a container that meets the requirements of state and federal law and is correctly labeled.

This Bill:

1) Authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. (H&S 150004 Added)

2) Requires a county that establishes a repository and distribution program would be required to establish procedures for all of the following:

a. Establishing eligibility for medically indigent patients who may participate in the program.

b. Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

c. Ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacist by ensuring, at a minimum, all of the following:

i. That only those drugs that are received and maintained in their unopened, tamper evident packaging are dispensed.

ii. That any drugs received have not been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia or the product manufacturer.

iii. That any drugs received are dispensed prior to their expiration date.

iv. That reasonable methods have been established to ensure that drugs received have not been in the possession of any individual member of the public.

v. That a pharmacist may use his or her discretion and best judgment in deciding whether or not to accept any donated drug.

vi. That records are kept for at least three years from the date that any drug is received or dispensed, whichever is later, pursuant to this division.

vii.

(H&S 150004 Added)

3) Authorizes drug manufacturers to donate excess or surplus unused prescribed medications to programs established by counties. (H&S 15002 Added)

Comment:

1) Author's Intent. The author's intent is to provide another avenue for low income individuals to obtain prescription.

2) Concerns. Staff is concerned that this bill establishes a framework to offer, on a county by county basis, a program that should be offered statewide, and it vest writing, what should be statewide standard procedures, with individual counties that choose to participate in the program. If enacted this measure would result in a patchwork of individually run programs throughout the state with different eligibility requirements for recipients and different procedures for the pharmacies, drug manufacturers, and health facilities that wish to participate in the program. If California were to establish a prescription drug repository and distribution program, the state would be best served if it copied programs in other states that have established similar programs.

3) Other States. At least five other states have established drug repository and distribution programs; these are: Okalahoma, Missouri, South Dakota, Wisconsin, and Louisiana. While no two states' programs are exact, there are commonalities among the programs; these commonalties are:

a) Establishment of a statewide program with statewide procedures.

b) Regulations for the implement the program are written by either the state's Board of Pharmacy or Department of Health. Regulations include the following not present in SB 798:

   i. The issuance of a program identification card for eligible recipients of the program.

   ii. Establishment of a handling fee to be charge to recipients of the program.

c) A list of formulary of drugs or class of drugs accepted for donation to the program.

d) The exclusion of controlled dangerous drugs from the program.

e) A provision in the enabling legislation that pharmacists, pharmacies, health facilities, drug manufacturers, and state agencies that participate in the program will not be subject to criminal or civil liability for injury, death, or property, for participating in the program.

4) Support & Opposition

Support: California Consumer Health Care Council
California Medical Association
City of Palo Alto
Clean Water Action
Santa Clara County Board of Supervisors
Santa Cruz County Health Department
Western Center on Law and Poverty

Opposition: None on file.

5) History.

2005

June 22	Read second time. To third reading.
June 21	Read second time. Amended. To second reading.
June 20	From committee: Do pass as amended. (Ayes 14. Noes 0.)
June 7	Set, first hearing. Held in committee and under submission.
May 26	To Com. on HEALTH.
May 16	In Assembly. Read first time. Held at Desk.
May 16	Read third time. Passed. (Ayes 30. Noes 6. Page 1040.) To Assembly.
May 10	Read second time. Amended. To third reading.
May 9	From committee: Do pass as amended. (Ayes 10. Noes 0. Page 953.)
Apr. 11	Set for hearing May 4.
Mar. 30	Withdrawn from committee. Re-referred to Com. on HEALTH.
Mar. 29	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 23	Set for hearing April 6.
Mar. 10	To Coms. on B., F. & I. and HEALTH
Feb. 24	From print. May be acted upon on or after March 26.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SB 798

As Amended June 21, 2005

SENATE THIRD READING

Majority vote

SENATE VOTE :30-6

HEALTH 14-0

Ayes:	Chan, Aghazarian, Berg, Cohn, Dymally, Chu, De La Torre, Jones, Montanez, Nakanishi, Negrete McLeod, Richman, Ridley-Thomas, Strickland

SUMMARY : Establishes a voluntary, county-option drug repository and distribution program to distribute surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Specifically, this bill :

1)Permits a county to establish, by local ordinance, a prescription drug repository and distribution program. Permits health facilities, pharmacies, and drug manufacturers, as specified, to donate excess or surplus unused prescribed medications to the program.

2)Requires a county that elects to establish a repository and distribution program pursuant to this bill to establish procedures for, at a minimum, all of the following:

a) Establishing eligibility for medically indigent patients who may participate in the program;

b) Ensuring that patients eligible for the program are not charged for any medications provided under the program;

c) Ensuring the privacy of individuals for whom the medication was originally prescribed; and,

d) Ensuring safe management of any medications collected by a licensed pharmacist by ensuring, certain minimum standards, as specified.

3)Provides immunity from civil and criminal liability, except in cases of gross negligence or bad faith, when donating,

accepting or dispensing prescription drugs is compliance with this bill.

FISCAL EFFECT : None

COMMENTS : According to the author, rapidly escalating prescription drug costs are increasingly putting needed pharmaceutical therapies beyond the reach of many of the state's citizens. The author maintains that at the same time, every year, California health facilities throw away hundreds of millions of dollars worth of perfectly good medications that were initially prescribed to someone else, but never used. The author insists that recent advances in packaging, preserving, and labeling have given pharmacists new capabilities to verify a medication's safety and ensure its integrity. In 2001, an article in the Journal of Family Medicine estimated that $1 billion a year in drugs prescribed for the elderly in the United States (U.S.) are thrown away.

Access to affordable prescription drugs is a growing problem in California and in other states. According to the Kaiser Family Foundation (KFF), almost a quarter of Americans under age 65 have no prescription drug coverage. According to the UCLA Center for Health Policy Research, nearly one in five Californians under age 65 lacked health coverage altogether in 2001, a substantial percentage of whom are not eligible for most public assistance or drug assistance programs due to excess income or assets. A 2003 KFF survey found that 37% of the uninsured, when they finally did see a doctor, did not fill a needed prescription because of cost. Of those who do have health coverage, over two million report that they do not have coverage for prescription drugs. Prescription drugs represent one of the fastest growing health care expenditures as drug prices continue to grow at roughly twice the rate of inflation in California and the rest of the U.S. Of the 50 drugs used most frequently by seniors, the average annual cost as of January 2003 was $1,439. The five most frequently prescribed medications for the elderly all had annual costs of between $500 and $1,500 per year. According to surveys, substantial percentages of seniors forego taking their medications due to the high cost. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over 20% and experienced higher rates of emergency room visits and hospital stays.

According to the National Conference of State Legislatures at least 25 states have enacted prescription drug recycling or repository programs for unused medications. While details of these laws vary, most allow return of prescription drugs in single use packaging from state programs, nursing homes, and

other medical facilities to be redistributed to needy residents. In 2000, the American Medical Association (AMA) looked at one such program in Oklahoma where nursing homes directed unused and unopened medicines back to pharmacies for distribution to indigent patients. According to AMA, there was an estimated $3 to $10 million a year in unused prescription drugs from such facilities in the state of Oklahoma. Oklahoma's population of 3.6 million is one-tenth California's.

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097